[Volume V, Appx04455 – Appx13184]

Nos. 22-1972, -1973, -1975, -1976

IN THE
United States Court of Appeals
FOR THE FEDERAL CIRCUIT

MASIMO CORPORATION,

Appellant,

v.

APPLE INC.,

Appellee.

APPEAL FROM THE PATENT TRIAL AND APPEAL BOARD
CASE NOS. IPR2020-01713, IPR2020-01716, IPR2020-01733, IPR2020-01737

JOINT APPENDIX

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May 10, 2023

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.,
Petitioner,

-against-

MASIMO CORPORATION,

Patent Owner.

Case Nos.
IPR 2020-01520
U.S. Patent 10,258,265

IPR 2020-01537
U.S. Patent 10,588,553
IPR 2020-01539
U.S. Patent 10,588,554

VOLUME 1

VIDEO-RECORDED DEPOSITION OF

VIJAY K. MADISETTI, PH.D.

Zoom Recorded Videoconference

08/01/2021

11:01 a.m. (EDT)

REPORTED BY: AMANDA GORRONO, CLR
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APPLE 1054
Apple v. Masimo
IPR2020-01713

(Whereupon, Exhibit 1001, U.S Patent No. 10,258,265 B1, was identified.)
A. Could you please upload that?
Q. Yep.
MR. SMITH: Billy, if you wouldn't mind giving that to him.
THE TECH: Okay. It should be in there now. You may need to refresh if you don't see it.
THE WITNESS: Yeah, I'm getting there. Could you please post that link, Mr. Videographer. Once again, I think I've closed my browser -- no, no, I have it. Okay.
A. Okay. Counsel, I have opened up the patent '265. And could we please remind me as to the specific question you had?
Q. Sure. I, I had asked: What is scattering, with respect to light?
A. So in the '265 patent it describes in Column 21, a mention of scattering by tissue in Line 25 of Column 21. So in a nonlimiting manner, it describes how light could be scattered by tissue.

Q. And what would that scattering of the light by the tissue entail?

A. It could reflect the light back, as an example.

Q. So like backscattering?

A. I said light could be reflected back, as an example.

Q. Would that be, would that be referred to as backscattering?

A. You see that term somewhere? I mean, all I can say, and I'm -- I offered you an example of reflection as an example of scattering in this particular --

Q. Was a reflection also referred -- sorry.

A. -- in this particular of, in this particular context.

Q. Are you familiar with the term backscattering?

A. I don't believe the, the '265 covers that term, describes or mentions that term. I don't believe my Declaration mentions that term.

the measurement site would be focused by the convex surface. That's how they would understand from this figure and also from the combinations that are asserted.

Q. What does it mean for light to be collimated?

A. Are you specifically referring to a portion --

Q. I'm referring to Figure 14B, specifically the light rays 1420. I wanted to know if those -- I'll skip ahead.

Are those light rays collimated, if you're familiar with the term?

A. A POSA would understand that Figure 14B would apply to all types of light from the measurement site given the disclosures of the patent at issue, for example.

Q. So all types of light, regardless of the angle at which the light rays hit protrusion 605, would follow the path 1422 shown in Figure 14B?

A. My testimony is that a POSA, or a person of skill in the art, understanding the

disclosures of the '265, the '553, and the '554 patents, would understand that the specification and the figures teach that the convex surface would focus light of all kinds from the measurement site.

That's what a POSA would understand.

Q. But Figure 14B doesn't show light of all kinds, does it?

A. My testimony, again, is that a POSA, viewing Figure 14B in the context of the specification, would understand that it represents light from the measurement site that could include all kinds of light, including collimated or diffused light.

Q. Would light paths in a -- in diffuse light look like the paths 1420 in Figure 14B?

A. A POSA would understand that light would, as a general principle, condense towards the center, irrespective of the type of light, and that's consistent with the testimony of Mr. -- of Dr. Kenny, consistent with my own views of how a POSA would view the disclosures of the Masimo patents at issue, and also consistent with how a POSA would view the prior

art combinations that have been asserted in this matter.

Q. You said as "a general proposition" -- I'm sorry, let me get the exact language there, hold on. I don't want to paraphrase.

You said that "a POSA would understand that light would, as a general principle, condense towards the center, irrespective of the type of light"; is that correct?

A. That's one of the statements I made. I'm saying here that one -- a POSA would understand, viewing the disclosures in the '265, the '553 and the '554 patent, and the disclosure of Figure 14B, for example, to show that light from the measurement site -- light of all kinds from the measurement site would be focused or condensed towards the center; in this case, towards the detectors.

And that is -- and this is consistent with the testimony of Dr. Kenny and also my own opinions as to the view of a POSA, and it applies also to how a POSA would view the asserted prior art combinations in this matter.

Q. So you said "light of all kinds would be condensed towards the center" --

(Simultaneous speakers.)

A. Light of all kinds from the measurement site -- from the measurement site.

Q. Can you let me finish my question? Sorry.

A. I'm sorry.

Q. Yeah, I'm sorry. I just wasn't finished. Let's see.

So you said, "Light of all kinds would be condensed towards the center." Does that -- am I to understand that light of all kinds includes light of all angles of incidence to the protrusion 605?

A. Again, I think I stated that earlier. The specification and the figures teach and disclose to a POSA that the convex surface would condense or focus light, and that's what is being taught to a POSA in view of the figure and the corresponding portions in the specification.

Without qualifying any particular

type of angle, they would generally be condensed or focused towards the center.

Q. What do you mean by "focused towards the center"?

A. That means condensed or directed towards the center.

Q. What do you mean by "towards the center"?

A. They would -- the nature of the convexity would direct it in a path. For example, that -- if you look at, if you look at Paragraphs 118, 119, and 120 of Dr. Kenny's Declaration in this matter, he's drawn a number of figures that indicate what is an example of how light is condensed to the center.

So he testifies, and if you walk with me, that with respect to the figures in the Paragraphs 119, that, that the incoming light is condensed towards the center. And it goes further, explaining how the total path length is shortened.

And in the figure below Paragraph 120, it clearly shows that the purple line

referring to the entire time.

A. One second, let me see where I have that.

Q. So have you not been referring to the copy of the declaration that you downloaded?

A. No, no, no, because I have so many that -- the PDFs, that I was opening the -- that's it, 1520 -- yeah, that doesn't say 1520. It just says 2004, which is why I got confused. The other ones say 1539 and 1537.

Yeah, I have Exhibit 2004. You label them differently.

So what's the question, sir?

Q. One second. So my question was: Would light that was emitted by an emitter, such as an LED, follow the light paths 1420 in Figure 14B?

A. Again, my answer as I've given that before, a POSA would understand from the disclosures of 14B and the specification of the '265 patent, that the convex surface as shown in 14B would redirect the incoming light towards the center.

Q. That wasn't my question. That was --

my question was about light emitted by an LED and would the light emitted by the LED follow the light path 1420 in Figure 14B?
A. Again, I'm unsure as to your specific question. I was referring to Figure 14B, as disclosed in the '265 and in my view, a POSA would understand that as described in the text that I cited to, the light from the emitters as described in 14B would be coming in from the measurement site and a POSA from the disclosure of the '265, including the figure, would understand that the convex surface would redirect and condense light towards the center.
Q. So again, I've asked this a couple of times, but the light rays 1420, you're saying that that is a representation of what -- of how the light would be reflected by the tissue at the tissue measurement site, correct?
A. As I said, my opinion is that a POSA, viewing Figure 14B and 1420 in the light of the specification, would understand that Figure 20B -- Figure 14B would convey to a POSA that light from the measurement site would be redirected towards the

center as, for example, shown in 14B.

Q. You said "for example." So the paths shown in 14B are -- are an example of how light would behave when passing through the protrusion 605?

A. That's not my testimony. My testimony is the POSA would understand from Figure 14B and the supporting specification cites that are cited that 14B discloses that light from a measurement site would be redirected towards the center as I described in my Declarations.

Q. Regardless of the angle of incidence on the protrusion 605?

A. I didn't hear you, sir.

Q. I said regardless of the angle of incidence on the protrusion 605?

A. Again, my testimony is the same as before. A POSA viewing this figure would understand that it represents light from the measurement site. In, in view of the disclosures in the specification, it would tell a POSA that light from the measurement site would be redirected and condensed towards the center and this is, again, consistent to sworn

testimony of Dr. Kenny, as I cite to.

Q. So these are the only light paths that reflected light from the tissue measurement site would follow?

A. I think my testimony was pretty clear that a POSA viewing Figure 14B in light of the disclosures of the '265 specification and the related patents in this matter specification that it describes how light from the measurement site would be redirected or condensed towards the center. And that's also consistent with Dr. Kenny's testimony that I cite in the same section.

Q. So where would a POSITA understand the emitter to be located in Figure 14B?

A. A POSITA would understand that Figure 14B describes the light from the measurement site. It does not restrict or limit the positions of the emitters. It would apply, in light of the disclosures in the '265 to the general property of convex surfaces that redirect light towards the center.

Q. And that general property of

redirecting light towards the center, that would depend on the index of refraction of the material, correct?

A. All I can say is that a POSA viewing Figure 14B and the disclosures in the text of the specification and also the disclosures in the prior art asserted, asserted that this is consistent with redirecting or condensing light towards the center.

Q. What do you mean by "redirecting"?

A. Just redirecting. Changing the angle towards the center.

Q. So refracting?

A. All I can say is that redirecting means -- redirecting means moving the direction towards the center.

Q. Is refraction a form of redirection?

A. Yes, it's a form of redirection. It's an example of redirection.

Q. And in the case that the protrusion was refracting the light, the index of refraction of the material would determine how that redirection takes place, correct?

A. Again, I would disagree with that characterization in the manner that -- in the way I was describing, is that from the disclosures of 14B, it's very clear to a POSA that in light of the specification, that light from the measurement site is being redirected or condensed towards the center. And it's also clear from the record that Dr. Kenny's sworn testimony says the same thing, that light is condensed towards the center. So there's no dispute on this issue.

Q. I would take issue with that characterization. But I'll actually ask you: Have you reviewed the entire deposition transcript of Dr. Kenny?

A. I believe so.

Q. So you're familiar with all of his answers on this point?

A. I reviewed his Declaration, which I understand is his sworn testimony. I've reviewed his deposition transcript, and I believe that he has testified, even in his Declaration, as well as supported that in his deposition, quite clearly. And

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.

Petitioner,

v.

MASIMO CORPORATION,

Patent Owner.

Case IPR2020-01713
U.S. Patent 10,624,564

DECLARATION OF VIJAY K. MADISETTI, PH.D.

Masimo Ex. 2004
Apple v. Masimo
IPR2020-01713

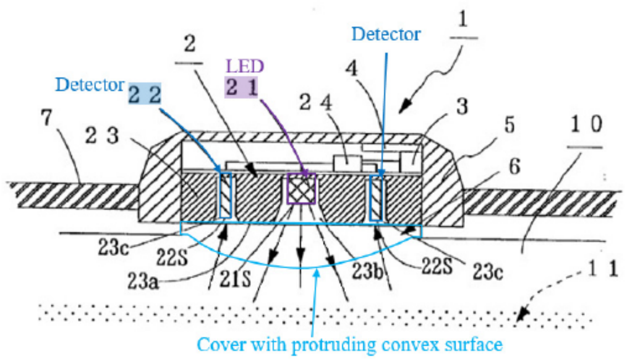
shaped cover to Aizawa's sensor would have a detrimental optical impact by directing light away from Aizawa's peripherally located detectors, resulting in reduced signal strength and decreased detection efficiency. Further a POSTIA would not have selected a convex shape for protecting Aizawa's sensor components because of the complications and problems associated with adding a convex surface to Aizawa's flat plate.

1. <u>A POSITA Would Have Understood That Ohsaki's Rectangular Board Would Not Work With Aizawa's Circular Sensor Arrangement</u>

a) <u>Modifying Ohsaki's Rectangular Board Would Eliminate The Limited Advantage Of Reduced Slipping Taught By Ohsaki</u>

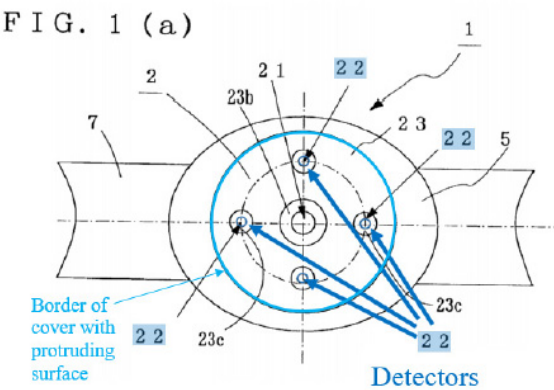
46. Dr. Kenny's combination changes Ohsaki's structure and eliminates the longitudinal shape that gives Ohsaki's rectangular board the ability to fit within the user's anatomy and prevent slipping. Ex. 1003 ¶70; Ex. 1009 ¶[0019]. Dr. Kenny's illustrated combination changes Ohsaki's rectangular board (discussed in Sections VII.A.1-2, above) and makes it circular so that it can cover Aizawa's holder 23 (which Dr. Kenny identified in blue in the figures below):

FIG. 1 (b)



Dr. Kenny's illustration of the combination of Ohsaki, Aizawa, and Goldsmith (Ex. 1003 ¶103)

FIG. 1 (a)

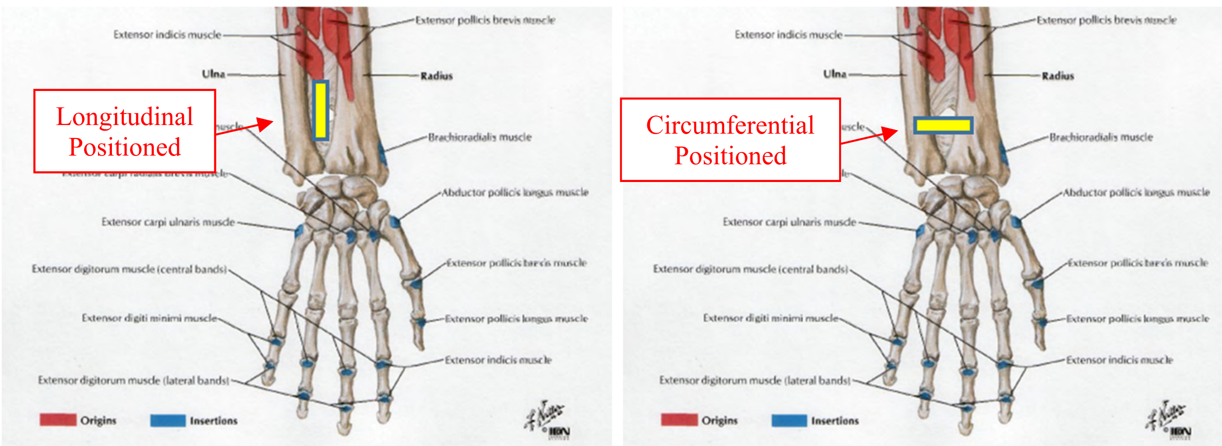


Dr. Kenny's illustration of Aizawa's circular sensor (Ex. 1003 ¶105)

47. Dr. Kenny asserts that a POSITA would have been motivated to add Ohsaki's rectangular board to Aizawa's circular sensor to improve adhesion. Ex. 1003 ¶70; *see also, e.g.*, ¶¶67, 103, 105. As an initial point, Ohsaki does not specifically discuss improving adhesion, and instead refers to a particular configuration that prevents slipping and various other configurations that have a tendency to slip. Ex. 1009 ¶¶[0006], [0010], [0019], [0023], [0025]. Dr. Kenny equates Ohaski's disclosure of a convex surface that prevents slippage with "improving adhesion." Ex. 1003 ¶67 (citing Ex. 1009 ¶[0025]). But Dr. Kenny's proposed modification eliminates the longitudinal shape that Ohsaki identifies as an important part of reducing slipping. Ex. 1009 ¶[0019].

48. Ohsaki places its linear, longitudinal sensor on the backhand side of a user's wrist to avoid interacting with bones in the wrist. *See* Ex. 1009 ¶[0006] (discussing need to avoid pressing on "two bones (the radius and the ulna)"),

¶[0024] ("the radius and the ulna inside the user's wrist 4 are not pressed"); *see also*, *e.g.*, ¶¶[0023]-[0024], Abstract, Title, Fig. 1 (Ohsaki device worn on back side of wrist). As illustrated below (left), the forearm bones (the radius and ulna) on the arm's backhand (or watch) side create a longitudinal opening at the junction between the wrist and forearm with no muscle insertions. Ex. 2010 at 49 (Plate 434). The radius and ulna, against which Ohsaki warns against pressing (Ex. 1009 ¶¶[0006], [0024]), are on either side of this longitudinal opening.



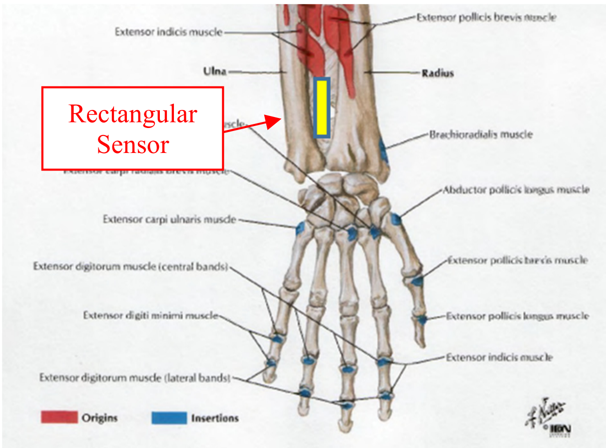
Anatomical drawing of the back side (posterior) of the hand, wrist, and forearm (partial view from Ex. 2010 at 49 (Plate 434))
Left: Conceptual view of how a rectangular sensor that is positioned in longitudinal direction on the wrist/forearm can avoid the radius and ulna
Right: Conceptual view of how the same rectangular sensor placed in the circumferential direction on wrist/forearm interacts with the radius and ulna

49. Ohsaki indicates that its sensor's longitudinal direction needs to be aligned with the longitudinal direction of the longitudinal opening of the user's arm to prevent slipping. Ex. 1009 ¶[0019]. If the sensor's longitudinal direction is aligned with the circumferential direction of the user's wrist, the undesirable

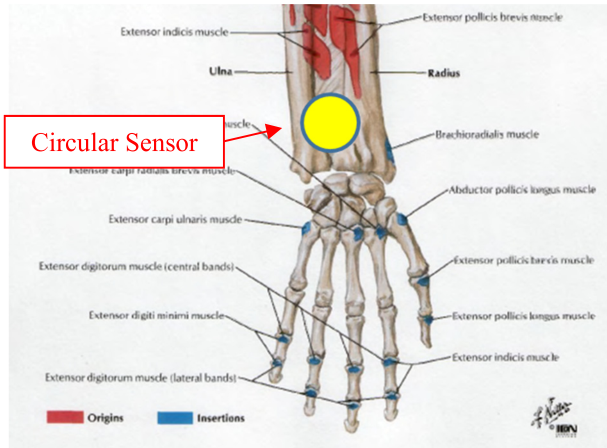
result is "a tendency [for Ohsaki's sensor] to slip off." Ex. 1009 ¶[0019]. As illustrated above (right), a rectangular structure like Ohsaki's sensor and board that is aligned with the circumferential direction of the user's wrist undesirably interacts with the radius and ulna, which Osaki warns against. Ex. 1009 ¶¶[0006], [0024]. In contrast, a rectangular structure aligned with the longitudinal direction of the user's wrist can avoid pressing against the radius and ulna.

50. Thus, a POSITA would have understood that changing the shape of Ohsaki's rectangular board to circular would not preserve its ability to prevent slipping. Instead, if Ohsaki's rectangular board were changed into a circular shape, a POSITA would have believed it would have resulted in slipping, and thus eliminated the advantage of Ohsaki's board. This is because a circular shape extends equally in all directions, including in the circumferential direction of the user's wrist, which Ohsaki explains results in slipping. Ex. 1009 ¶[0019]. As a result, a circular shape cannot be placed in a longitudinal direction and thus cannot align with the longitudinal direction of the user's wrist, as taught by Ohsaki. As illustrated below, unlike a longitudinal sensor, a symmetrical circular shape (with a diameter equal to the long side of the rectangle, below left) would not fit within the user's anatomy in a way that it could avoid undesirably pressing against the user's radius and ulna, which Ohsaki cautioned against.

Ohsaki's Longitudinal Teachings



Dr. Kenny's Proposed Combination



Anatomical drawing of the back side (posterior) of the hand, wrist, and forearm (partial view from Ex. 2010 at 49 (Plate 434))
Left: Conceptual view of how a rectangular sensor that is positioned in longitudinal direction on the wrist/forearm can avoid the radius and ulna
Right: Conceptual view of how a circular sensor with the same diameter as the length of the rectangular board interacts with the radius and ulna

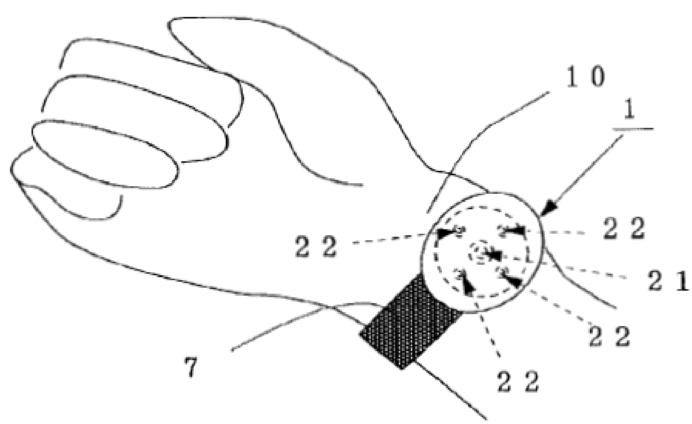
51. Because a symmetrical circular shape will press on the user's arm in all directions, it will interact with the user's bone structure. Ohsaki teaches that such interactions with the user's anatomy are undesirable and result in slipping. Ex. 1009 ¶¶[0006], [0023]-[0024].

52. Dr. Kenny did not discuss Ohsaki's disclosure that when Ohsaki's rectangular sensor was placed in one orientation (up-and-down the arm), it helped prevent slipping. Ex. 1009 ¶[0019]. Dr. Kenny also did not discuss Ohsaki's explanation that rotating the sensor 90 degrees, such that the long direction points in the circumferential direction of the user's wrist, the sensor "has a tendency to slip." Ex. 1009 ¶[0019].

a) <u>Aizawa's Flat Acrylic Plate Improves Adhesion On The Palm Side Of The Wrist</u>

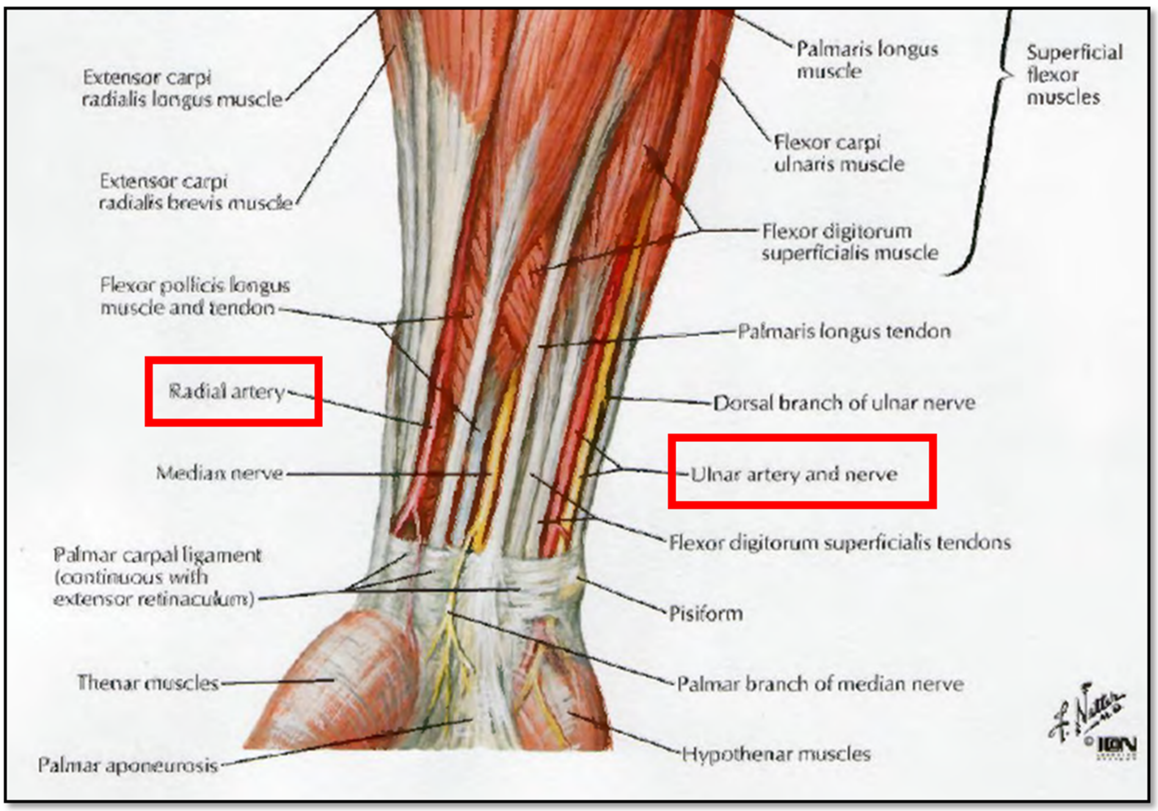
61. Aizawa (Fig. 2 below) discloses a sensor used on the palm side of the wrist. Aizawa's sensor uses a flat acrylic cover with a circular array of multiple detectors surrounding a single LED. Aizawa explains its sensor functions by "irradiating the artery of the wrist" and is thus shown worn on the palm side of the wrist, which is close to the large radial and ulnar arteries. Ex. 1006 ¶[0002]; *see also* ¶¶[0007], [0009], [0026], [0027], [0036], Fig. 2. Aizawa illustrates its sensor's positioning on the palm side, described by Aizawa as the "inner side," of the user's wrist. Ex. 1006 Fig. 2; Ex. 1006 ¶[0026]. Aizawa explains: "As shown in FIG. 2, a subject carries the above pulse rate detector 1 on the inner side of his/her wrist 10 with a belt in such a manner that the light emitting face 21s of the light emitting diode 21 faces down (on the wrist 10 side)." Ex. 1006 ¶[0026].

FIG. 2



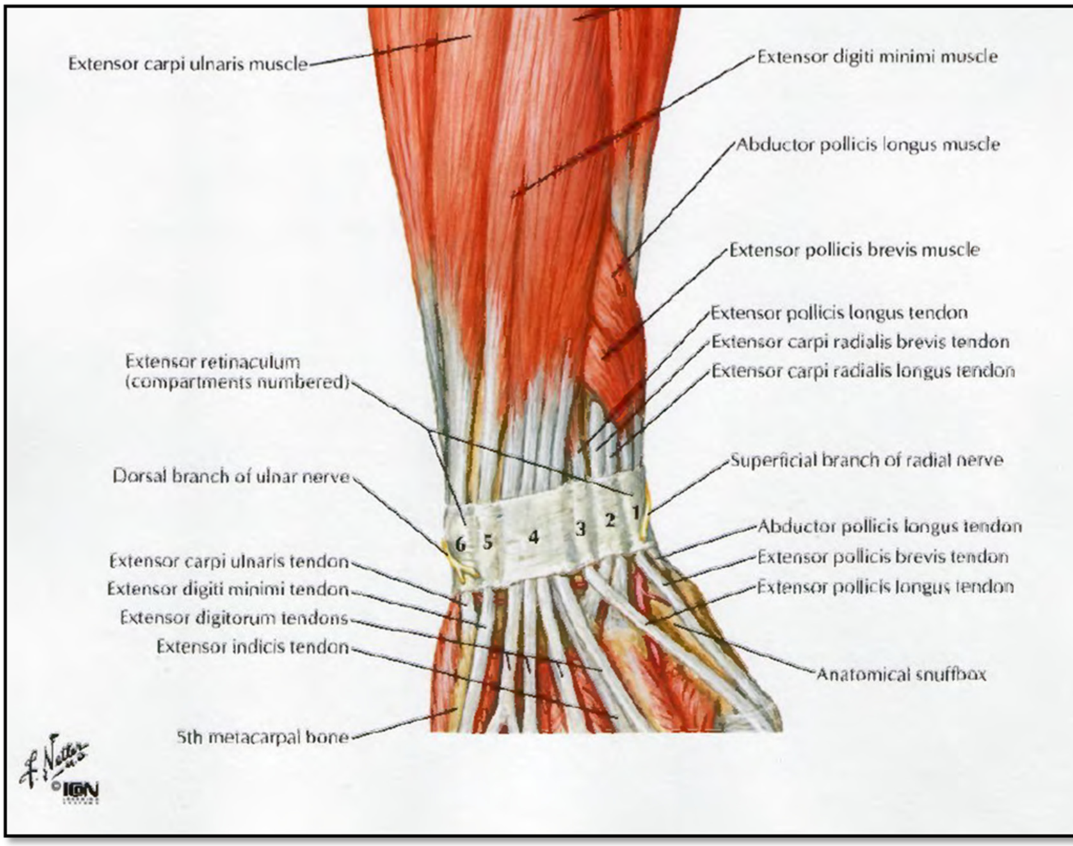
Aizawa's palm-side sensor positioning
on the palm side of the wrist (Ex. 1006 Fig. 2, ¶[0026])

62. As illustrated in Aizawa Figure 2, Aizawa's sensor takes measurements from the palm side of the wrist, near the artery. As shown below, the ulnar and radial arteries are near the surface on the palm side of the wrist, and Aizawa's figure shows its sensor positioned towards the thumb side of the wrist, which corresponds to the location of the radial artery. Ex. 2010 at 44 (Plate 429) (showing radial and ulnar arteries in superficial layer of the anterior (palm side) of wrist); *see also* 71 (Plate 456) (showing arteries on palm side of upper limb).



Superficial layer of palm side (anterior) forearm and wrist, showing that the radial and ulnar arteries are close to the surface
(partial view) Ex. 2010 at 44 (Plate 429), annotated

63. In contrast, as shown in the figure below, the radial and ulnar arteries are not near the surface of the wrist and forearm's back side.



Superficial layer of back side (posterior) of forearm and wrist
(partial view) Ex. 2010 at 42 (Plate 427)

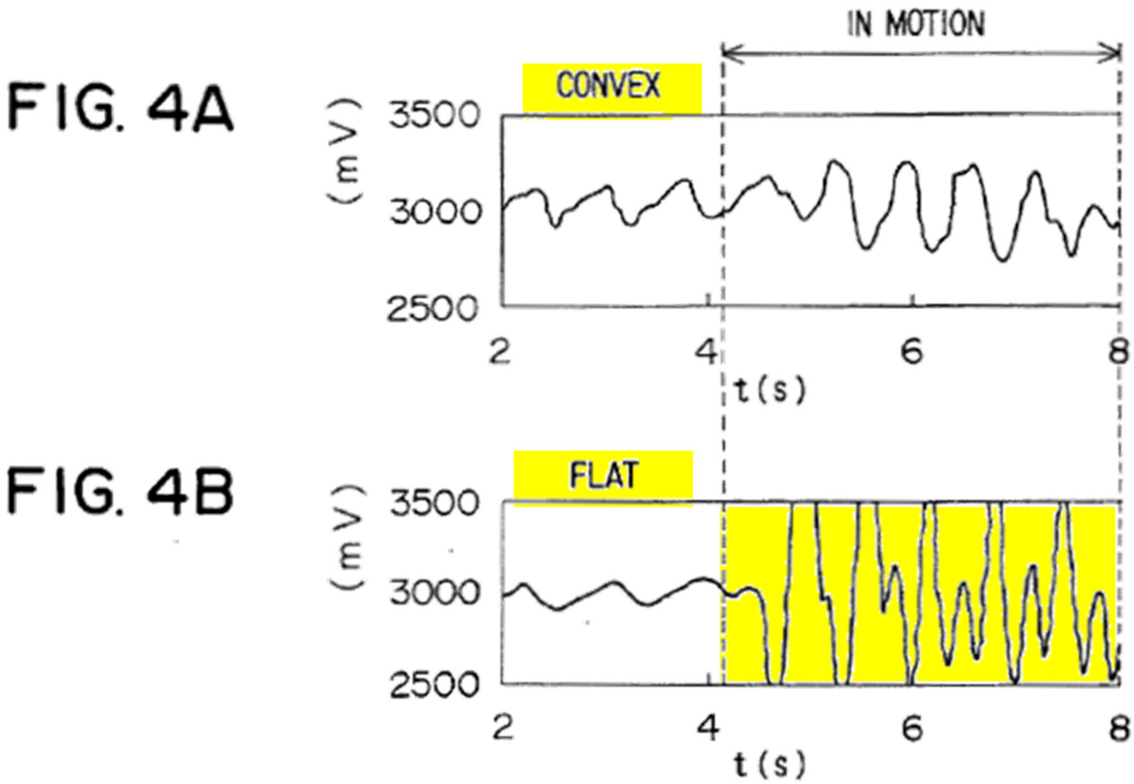
64. Thus, a POSITA would have understood that Aizawa teaches its wrist-worn sensor is used on the palm side of the wrist and measures an optical signal from an artery, and thus should be positioned above, *e.g.*, the radial artery as shown in Aizawa Figure 2's sensor placement. Aizawa repeatedly confirms the positioning at "the artery of the wrist," explaining:

- Its sensor functions by "irradiating the artery of the wrist with light." Ex. 1006 ¶[0002].
- Its sensor detects "light output from a light emitting diode and reflected from the artery of a wrist of a subject." Ex. 1006 ¶[0009].
- That a belt fastens its sensor so "the acrylic transparent plate 6 becomes close to the artery 11 of the wrist 10." Ex. 1006 ¶[0026].
- That the light detected by its sensor's photodiodes "is reflected by a red corpuscle running through the artery 11 of the wrist 10." Ex. 1006 ¶[0027].
- That "the present invention…is constituted such that light output from a light emitting diode and reflected from the artery of the wrist…." Ex. 1006 ¶[0036].

65. As shown in the illustration below (left), Aizawa's sensor places detectors (red) symmetrically in a concentric circle around an emitter (green). Ex. 1006 Fig. 1A. Aizawa protects these optical components, which are in cavities, with a flat acrylic transparent plate (blue, below, right) placed on the top of the holder (23). Ex. 1006 ¶[0023], Fig. 1B; *see also* ¶[0024] (emitters and detectors "stored in cavities").

identified by Ohsaki corresponds to the irregular pattern shown in Figure 3B, compared to the pattern of measurements from the back side of the wrist shown in Figure 3A. For measurements using a convex board on the back side of the wrist, Ohsaki explains Figure 3A shows "the pulse wave is detected stably without being affected by the movement of the user's wrist...." Ex. 1009 ¶[0024].

72. Dr. Kenny does not cite or discuss Ohsaki's Figures 3A-3B when discussing the motivation for modifying Aizawa's palm-side sensor with a lens/protrusion similar to Ohsaki's board. Ex. 1003 ¶¶66-70; *see also* ¶¶103-105. Instead, Dr. Kenny discusses Ohsaki's Figures 4A-4B, which compares measurements using a sensor with a convex surface or a flat surface on the back (i.e., watch) side of the wrist. Ex. 1003 ¶¶68-69; *see also* ¶¶103-105.



Ohsaki Figs. 4A-4B comparing convex and flat surfaces
for measurements taken from the back side of the wrist (color added)

73. Ohsaki states that Figure 4B shows that when measurements taken from the back side of the wrist using a sensor with a *flat* surface, "the detected pulse wave is adversely affected by the movement of the user's wrist." Ex. 1009 ¶[0025]. Ohsaki also indicates that a board with a *convex* surface prevents "slip[ping] off the detecting position" on the back side of the wrist, as shown in Figure 4A. Ex. 1009 ¶[0025]; *see also* ¶¶[0023]-[0024] (comparing tendency to slip on front and back side of wrist). Figure 4A, which illustrates Ohsaki's convex sensor placed on the back side of the wrist, contrasts with the measurements shown in Figure 3B (which illustrates a convex surface slips on the palm side of

the wrist). Figure 4A is consistent with Figure 3A (which illustrates a convex surface has comparatively less motion signal on the back side of the wrist). Taken together, a POSITA would have understood that Ohsaki's convex surface may prevent slipping on the back side of the wrist, if it is positioned appropriately (e.g., in the correct orientation with the long side up-and-down the wrist). Ex. 1009 ¶¶[0019], [0023]-[0025], Figs. 3A-3B, 4A-4B.

74. The rest of Ohsaki's disclosure recognizes the limitations on any benefit derived from its convex surface. Ohsaki repeatedly specifies that its sensor "is worn on the back side of a user's wrist corresponding to the back of the user's hand." Ex. 1009 Abstract; *see also* Title ("Wristwatch-Type Human Pulse Wave Sensor Attached On Back Side Of User's Wrist"), ¶¶[0008] (The "sensor according to the present invention…is worn on the back side of the user's wrist corresponding to the back of the user's hand"), [0009] ("attached on the back side of the user's wrist by a dedicated belt"), [0016] ("worn on the back side of the user's wrist"), [0024] ("[T]he detecting element 2 is stably fixed to the detecting position of the user's wrist" when arranged on the back side of the user's wrist 4.). The only other possible location mentioned for placement of Ohsaki's sensor is "the back side of the user's forearm," which is adjacent to the wrist. Ex. 1009 ¶¶[0016], [0030]. Thus, in my opinion, for these reasons a POSITA would not

have been motivated to use Ohsaki's longitudinal board, which is designed to be worn on the back of a user's wrist, with Aizawa's palm-side sensor.

c) A POSITA Would Not Have Been Motivated To Eliminate The Identified Benefits Of Aizawa's Flat Adhesive Acrylic Plate By Including A Lens/Protrusion Similar To Ohsaki's Board

75. Dr. Kenny asserts that a POSITA would have been motivated to modify Aizawa's flat adhesive acrylic plate "to include a lens/protrusion, similar to Ohsaki's translucent board 8, so as to improve adhesion between the user's wrist and the sensor's surface, improve detection efficiency, and protect the elements within the PMD housing." Ex. 1003 ¶70. But a POSITA motivated to improve Aizawa's palm-side sensor would not have been motivated to add Ohsaki's convex board. As discussed above, Ohsaki teaches a POSITA that its convex board only provides advantages on the back side of the wrist, in a particular orientation. Ex. 1009 ¶¶[0019], [0025]. Ohsaki further teaches that on the palm side (front side) of the wrist, a sensor with a convex board, "has a tendency to slip off the detecting position of the user's wrist." Ex. 1009 ¶[0023], Figs. 3A-3B.

76. As discussed above, Aizawa teaches that a flat acrylic plate improves adhesion between the sensor and skin on the palm side of the wrist. *See* Sections VII.A.3, VII.B.2.a, above. Taken individually and together, both Ohsaki and Aizawa undermine Dr. Kenny's proposed addition of a convex lens/protrusion

similar to Ohsaki's translucent board to Aizawa's palm-side sensor to improve adhesion. Ex. 1003 ¶70; *see also, e.g.* ¶¶103-105. This is because, as explained above (Sections VII.B.2.a-b): (1) Aizawa teaches a ***flat*** acrylic plate ***improves*** adhesion on the wrist's ***palm*** side; (2) Ohsaki teaches a ***convex*** board "has a tendency to ***slip***" on the wrist's ***palm*** side. As a result a POSITA reading Aizawa and Ohsaki would have affirmatively avoided modifying Aizawa's flat acrylic plate—which is taught to improve adhesion at Aizawa's sensor location on the palm side of the wrist—with a convex lens/protrusion similar to Ohsaki's convex board because Ohsaki's convex board is taught to slip on the palm side of the wrist where Aizawa's sensor is positioned. The table below summarizes these teachings.

	Front (Palm) Side	**Back Side**
Flat	Flat acrylic plate improves adhesion Ex. 1006 (Aizawa) ¶[0013]; *see also* ¶¶[0026], [0030], [0034], Fig. 1B **(Aizawa's sensor)**	Tends to slip Ex. 1009 (Ohsaki) ¶[0025], Figs. 4A-4B
Convex	Tends to slip Ex. 1009 (Ohsaki) ¶[0023], Figs. 3A-3B	Rectangular convex board prevents slipping Ex. 1009 (Ohsaki) ¶¶[0024]-[0025], Figs. 4A-4B **(Ohsaki's sensor)**

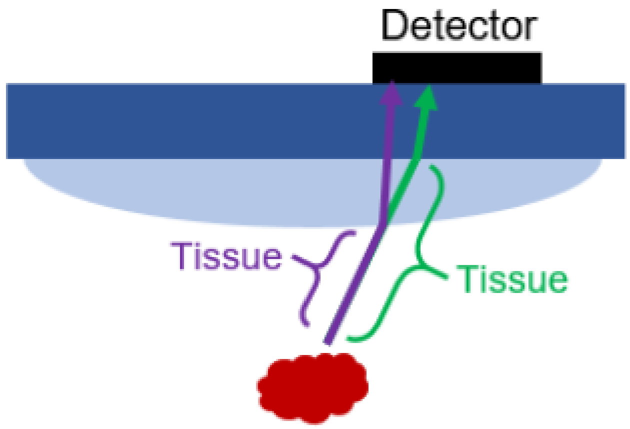
77. Dr. Kenny only considers Ohsaki's discussion of the impact of a convex versus flat surface on the back side of the wrist. *See, e.g.,* Ex. 1003 ¶¶67-

3. A POSITA Would Not Have Been Motivated To Reduce The Measured Optical Signal By Adding A Convex Lens To Aizawa's Sensor

79. Dr. Kenny's proposed combination is also problematic because Dr. Kenny detrimentally modifies Aizawa's flat cover to include a convex "lens/protrusion" positioned over peripheral detectors surrounding a centrally located emitter. Ex. 1003 ¶¶70, 103-105. As discussed below, a POSITA would have understood that a convex "lens/protrusion" would direct light away from the detectors and thus result in decreased light collection and optical signal strength at the peripheral detectors — not increased signal strength as Dr. Kenny asserts. *See* Ex. 1003 ¶68 (arguing that the convex surface of the translucent board of Ohsaki "increases the strength of the signals").

a) A POSITA Would Have Understood That A Convex Cover Directs Light To The Center Of The Sensor

80. Petitioner and Dr. Kenny both admit that a convex cover condenses light passing through it towards the center of the sensor and away from the periphery. Petitioner and Dr. Kenny both illustrated this phenomenon in a petition filed against a related patent. In the Petition in IPR2020-01520 (Ex. 2019), Petitioner explained that a convex cover redirects light coming into the convex surface towards the center, as shown in Petitioner's figure below:



Petitioner's illustration from a related IPR showing that light hitting a convex surface is directed more centrally than light hitting a flat surface (Ex. 2019 at 45)

81. In his declaration in IPR2020-01520 (Ex. 2020), Dr. Kenny likewise confirmed that when using a convex surface as a lens, "the incoming light is 'condensed' toward the center." *See, e.g.,* Ex. 2020 at 69-70 (¶119); *see generally* Ex. 1003 ¶¶118-120, 199-201. Dr. Kenny included the same illustration as Petitioner, which shows light passing through a convex surface is directed more towards the center, as compared to a flat surface. *See, e.g.*, Ex. 2020 at 69-71 (¶118-120).

82. The '564 Patent also confirms these admissions that a convex surface condenses light away from the periphery and towards the sensor's center. Figure 14B (below) "illustrates how light from emitters (not shown) can be focused by the protrusion 605 onto detectors." Ex. 1001 36:12-15. "When the light rays 1420 enter the protrusion 605, the protrusion 605 acts as a lens to refract the rays into rays 1422." Ex. 1001 36:23-25. As shown by Figure 14B of the '564 Patent,

the convex shape directs light from the periphery toward the center. Ex. 1001 Fig. 14B.

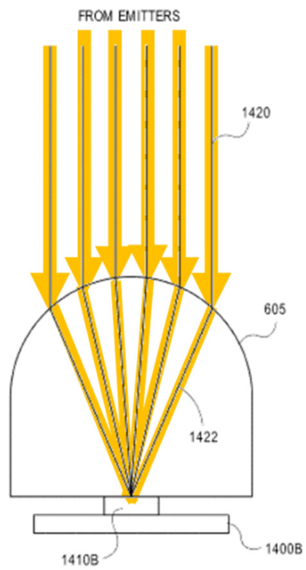
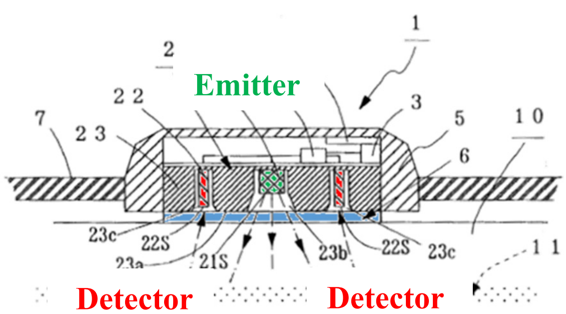


Illustration from the '564 Patent at issue, showing that light hitting a convex surface is directed towards the center
'564 Patent (Ex. 1001) Fig. 14B (highlighting added to show direction of light)

83. Accordingly, Petitioner, Dr. Kenny, and the '564 Patent all support that a POSITA would have understood that a convex lens/protrusion would direct incoming light towards the center of the sensor, as compared to a flat surface. In my opinion, a POSITA would have believed that light passing through a convex surface would have been directed to a more central location as compared to light passing through a flat surface. This would have been viewed as a detrimental result because, as discussed in the next section below, Aizawa's detectors are at the periphery of the sensor.

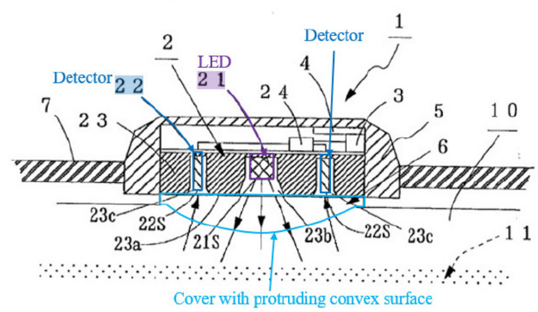
b) <u>A POSITA Would Not Have Been Motivated To Direct Light Away From Aizawa's Detectors</u>

84. Dr. Kenny asserts that a POSITA would have been motivated to modify Aizawa's flat adhesive acrylic plate with "a lens/protrusion" for improved detection efficiency. Ex. 1003 ¶70. As illustrated below, Aizawa has peripherally located detectors (in red, below left) and a centrally located emitter (in green, below left) under a flat acrylic adhesive plate (in blue, below left). Ex. 1006 Fig. 1B; *see also, e.g.*, ¶¶[0009], [0026]-[0027], [0033], [0036]. Dr. Kenny's combination introduces a convex "lens/protrusion" (in blue, below right) over Aizawa's peripherally located detectors and centrally located light source (*see, e.g.*, Ex. 1003 ¶70):



Aizawa Fig. 1B (cross-section)
Red: detectors; Green: emitter,
Blue: flat plate

FIG. 1 (b)

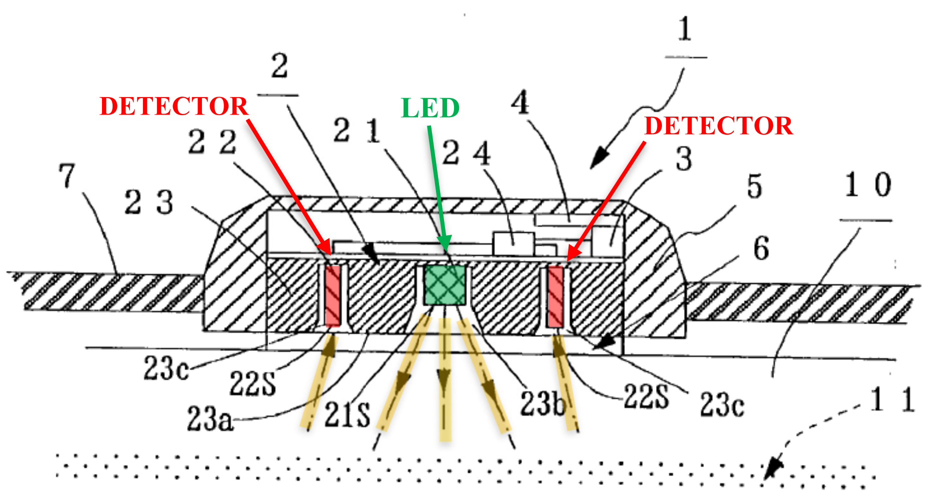


Dr. Kenny's proposed modifications
(Ex. 1003 ¶70)

Aizawa (Ex. 1006 Fig. 1B) (color added) (left) versus
Dr. Kenny's proposed combination (Ex. 1003 ¶70) (right)

85. Dr. Kenny asserts that Ohsaki's board "increases the strength of the signals obtainable by Ohsaki's PMD." Ex. 1003 ¶68; *see also* ¶54. However, as

discussed above (Section VII.B.3.a), a POSITA would have believed that adding a convex lens/protrusion to Aizawa's flat adhesive acrylic plate would direct light away from the combination's detectors that are located on the periphery. Aizawa illustrates that the light reaching Aizawa's detectors must travel from the center emitter to the outer periphery of the detectors. Ex. 1006 Fig. 1B, ¶[0027]. Aizawa shows the light path as leaving a single centrally located emitter, passing through the body, and reflecting back to periphery-located detectors (light must travel from the center emitter to the outer periphery to the detectors. Ex. 1006 Fig. 1B, ¶[0027]):



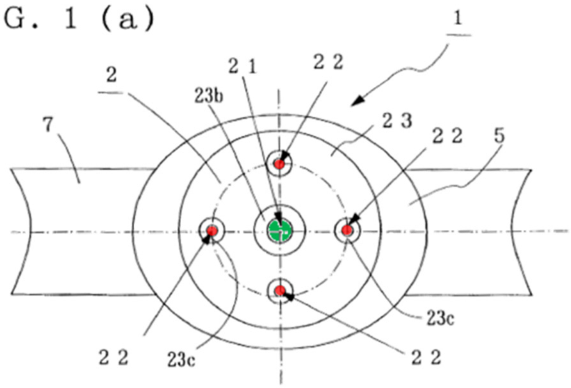
Aizawa Fig. 1B (cross-sectional view, color added)

86. Because of the configuration of Aizawa's sensor, with its central emitter and peripheral detectors, and the illustrated light path that requires light from the central emitter to reach the peripheral detectors, a POSITA would have understood that a change directing light to a more central location would decrease

the optical signal at Aizawa's peripheral detectors. Ex. 1006 ¶¶[0026], [0030] (discussing benefits of Aizawa's flat "plate"). Because a POSITA would have believed that adding a convex lens/protrusion would have redirected light to a more central location as compared to Aizawa's flat adhesive acrylic plate, a POSITA would have concluded that Dr. Kenny's proposed modification would decrease light-collection efficiency at Aizawa's peripheral detectors. Thus, I disagree with Dr. Kenny that a POSITA would have been motivated to modify Aizawa's flat plate to add a lens/protrusion similar to Ohsaki's translucent board based on the belief that it would have improved detection efficiency or otherwise increased signal strength. Ex. 1003 ¶70. As discussed above (Section VII.B.3.a) Dr. Kenny, the Petitioner, and the '564 Patent all support that a POSITA would have believed that adding a convex lens/protrusion would result in the light gathered and refracted to a more central location, and thus away from Aizawa's peripheral detectors, as compared to Aizawa's existing flat plate.

87. In addition, the addition of a convex lens/protrusion similar to Ohsaki's is particularly problematic because both Aizawa and Dr. Kenny's illustration of his combination include small detectors with small openings surrounded by a large amount of opaque material. Ex. 1006 Figs. 1A, 1B, 2; *see, also, e.g.*, Ex. 1003 ¶¶70, 80, 100, 103, 125, 129, 130, 163 (Dr. Kenny's

illustrations). Aizawa's top-down view confirms the detectors' small size. Ex. 1006 Fig. 1A.



Aizawa's Features

- **Green**: central emitter (21)
- **Red**: peripheral detectors (22)

Aizawa's sensor, showing small detectors (Ex. 1006 Fig. 1A), color added)

88. Thus, Dr. Kenny provides no evidence that a POSITA would have expected a convex lens/protrusion similar to Ohsaki's board to improve detection efficiency at Aizawa's peripheral detectors and increase signal strength. Ex. 1003 ¶¶68, 70. Instead, as explained above (Section VII.B.3.a), a POSITA would have expected that changing Aizawa's flat acrylic plate to a convex lens/protrusion similar to Ohsaki's board would reduce the amount of light gathered and refracted to Aizawa's peripheral detectors. The optical changes resulting from modifying Aizawa's flat surface to include a convex lens/protrusion similar to Ohsaki's board are thus another reason why a POSITA would not have been motivated to make that change.

Aizawa's flat adhesive acrylic plate, which already protects the elements within the sensor housing and does not introduce the complications and concerns arising from a convex shape.

C. Goldsmith Does Not Provide A Motivation To Combine Ohsaki and Aizawa

91. Dr. Kenny provides that "a POSITA would have been motivated and found it obvious to incorporate Aizawa's wrist-worn pulse wave sensor with a protruding convex surface (as taught by Ohsaki) into Goldsmith's integrated wristworn WCD that includes, among other features, a touch screen, network interface." Ex. 1003 ¶[0077]. Dr. Kenny does not, however, state that Goldsmith addresses the deficiencies in his proposed combination of Ohsaki and Aizawa. Thus, Dr. Kenny's addition of Goldsmith to the combination of Aizawa and Ohsaki does not provide a motivation to combine Aizawa and Ohsaki nor demonstrate that claim 1 is obvious in view of Aizawa, Ohsaki, and Goldsmith.

D. The Challenged Dependent Claims Are Nonobvious Over Ground 1

92. As discussed above, in my opinion claim 1 would not have been obvious over the cited references of Ground 1. In addition, in my opinion, the dependent claims would be nonobvious for at least the same reasons. *See* Sections VII.A-C, above.

93. In addition, for the reasons discussed below, dependent claims 16 and 17 are non-obvious for additional reasons. Claim 16 ultimately depends from

claim 1 and recites: "wherein the protruding convex surface protrudes a height between 1 millimeter and 3 millimeters." Claim 17 depends on claim 16 and recites: "wherein the protruding convex surface protrudes a height greater than 2 millimeters and less than 3 millimeters." The '564 Patent provides that particular exemplary convex shapes improve signal strength. Ex. 1001 20:25-34. The '564 Patent discloses: "For example, in one embodiment, a convex bump of about 1 mm to about 3 mm in height and about 10 mm^2 to about 60 mm^2 was found to help signal strength by about an order of magnitude versus other shapes." Ex. 1001 20:29-33. Thus, the '564 Patent explains that an appropriately sized protrusion can dramatically increase the accuracy of the measurements. Ex. 1001 20:25-34.

94. Dr. Kenny identifies no corresponding teaching in Ohsaki, Aizawa, or Goldsmith. Ex. 1003 ¶¶[0146]-[0148]. Instead, Dr. Kenny states when "incorporating Ohsaki's teachings, a POSITA would have found it obvious that a device designed to fit on a user's wrist would be on the order of millimeters," and "there would have been a finite range of possible protruding heights, and it would have been obvious to select a protruding height that would have been comfortable to the user." Ex. 1003 ¶¶[0147]-[0148]. But nothing in the grounds references discloses a protrusion with a height either between 1 millimeter and 3 millimeters

or greater than 2 millimeters and less than 3 millimeters would have been beneficial, as the inventors discovered.

95. Dr. Kenny suggests two references, Mendelson 2006 (Ex. 1010) and Mendelson 1988 (Ex. 1014), include disclosures of sensor sizes. Ex. 1003 ¶[0147]. But neither Mendelson 2006 nor Mendelson 1988 disclose a cover, let alone a cover with a protrusion. Ex. 1010 Fig. 1 (no view of cover); Ex. 1014 Fig. 2B (showing flat layer of epoxy encapsulating optical components). The flat surface of encapsulating epoxy used with Mendelson 1988's sensor would not have informed or motivated a POSITA to include a cover, much less a cover with a convex protrusion of a particular height.

96. Dr. Kenny seems to select Mendelson 2006 and Mendelson 1988 because they discuss similarly sized sensors (22 mm diameter and 19x19 mm square), which Dr. Kenny argues would also be used with a wrist-worn device. Ex. 1003 ¶[0147]. But both Mendelson 2006 and Mendelson 1988 are forehead sensors, not wrist sensors. Ex. 1010 Abstract ("wireless wearable pulse oximeter developed based on a small forehead mounted sensor"); Ex. 1014 at 1 ("SpO_2 obtained from the forehead"). Dr. Kenny provides no basis to select one sensor size over another or select one protrusion height instead of any other. Indeed, Ohsaki explains that its sensor's width and length—including the board—are important but says nothing about the height of the board. *See* Ex. 1009 ¶[0019]

(“the length of the detecting element 2 from the right side to the left side in FIG. 2 is longer than the length from the upper side to the lower side”).

97. Dr. Kenny also cites Kondoh, which Dr. Kenny suggests “describ[es] a protrusion…that causes a subject’s tissue ***to deform*** by a depth of about 2 to 20 mm.” Ex. 1003 ¶[0147] (citing Ex. 1023, emphasis added). But Kondoh states ***the protrusion’s height is 5 mm***, which is outside of the claimed range. Ex. 1024 12:33-39, 13:51-55, 14:66-15:3, 16:15-19, 17:25-28, 26:10-14. In addition, Kondoh is contrary to the proposed cover because Kondoh embeds its optical components (11, 12) on top of the “protrusion part” in direct contact with the user’s skin (4). *See, e.g.,* Ex. 1024 13:62-64 (“placed in the protrusion”), Fig. 6. Finally, Petitioner references Otanagi (Ex. 1026), but Dr. Kenny does not reference Otanagi. Pet. 78; Ex. 1003 ¶¶[0146]-[0148]. Petitioner suggests that Otanagi discloses a “distance between a lower surface of the watch housing and convex surface being 3 mm.” Pet. 78. But the LED and photodetector in Otanagi are placed on the top of the “convex surface” “as close as possible to the biological body surface.” Ex. 1026 ¶[0053]; *see also id*. Fig. 5, Fig. 7. This detail is not included in Petitioner’s analysis. Contrary to Petitioner’s suggestions, to the extent a POSITA would have found Kondoh and Otanagi relevant at all, both Kondoh and Otanagi would have led a POSITA to eliminate any protruding convex surface on a cover so that the emitter and detector are placed “as close as

possible to the biological body surface." Ex. 1026 ¶[0053]; *see also* Fig. 7 (illustrating a flat and very thin glass cover (23) over the LED (5) and detector (6)); *see also* Ex. 1024 13:62-64 ("placed in the protrusion"), Fig. 6.

98. Dr. Kenny also offers testimony to support his assertions without citing specific evidence. Ex. 1003 ¶[0148]. In particular, Dr. Kenny provides no support for his opinion that a height either between 1 millimeter and 3 millimeters or greater than 2 millimeters and less than 3 millimeters "provide[s] a comfortable cover…that prevents slippage." Ex. 1003 ¶[0148]. Such unsupported testimony does not show that a POSITA would select a "protruding convex surface protrudes a height between 1 millimeter and 3 millimeters" or a "protruding convex surface protrudes a height greater than 2 millimeters and less than 3 millimeters." In my opinion, a POSITA would not have found it obvious to include a cover with a protruding convex surface "wherein the protruding convex surface protrudes a height between 1 millimeter and 3 millimeters" or "wherein the protruding convex surface protrudes a height greater than 2 millimeters and less than 3 millimeters" based on the cited references of Ground 1.

VIII. GROUNDS 2-3 FAIL FOR THE SAME REASONS AS GROUND 1

99. Grounds 2-3 only address dependent claims and do not fix the deficiencies in Ground 1. These dependent claims are thus nonobvious for the

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.,	)
	) IPR NO. 2020-1520
Petitioner,	) US PATENT NO: 10,258,265
	)
-against-	) IPR NO. 2020-1537
	) US PATENT NO: 10,588,553
MASIMO CORPORATION,	)
	) IPR NO. 2020-1539
Patent Owner.	) US PATENT NO: 10,588,554

VIDEO-RECORDED DEPOSITION OF

THOMAS WILLIAM KENNY, JR. PH.D.

VOLUME 1

Zoom Recorded Videoconference

04/22/2021

9:02 a.m. (Pacific Daylight Time)

REPORTED BY: AMANDA GORRONO, CLR

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Masimo Ex. 2006
Apple v. Masimo, IPR2020-01713

art, looking at Figure 2 from Inokawa, would believe the lens-like feature provides the benefit of increased light at the center detector, correct?

MR. SMITH: Objection; form.

Q. I think I just repeated my last question, which --

A. I know. Again, I feel like I'm repeating all my answers. It's -- you know, one would understand that this convex lens-like shape increases light-collection efficiency. The shape provides this benefit by refracting and concentrating the light coming in through the acrylic plate after being reflected by the light. Yes, I think that's what I've been saying.

Q. Right. The part I'm focusing on that I think you agree with but you don't specify in your answer is that it provides this benefit by concentrating light towards the detector in the center, correct?

MR. SMITH: Objection; form.

A. Yeah. Inokawa teaches that the lens makes it possible to increase the light-gathering

ability and particularly for -- with respect to his own illustration, yes.

Q. Okay. And so a person of ordinary skill in the art, looking at Figure 2 of Inokawa, would believe that the lens-like feature concentrates light toward, toward the center detector, correct?

MR. SMITH: Objection; form.

A. So I want to be careful not to make a statement that's too general here, and that's, that's why I'm hesitating. They have other examples.

For example, Aizawa, where the detectors are not in the center, they are scattered around the perimeter. I'd say for a case of this particular alignment in Inokawa where the center axis of the lens and the detector are aligned, that one of ordinary skill in the art would understand that that arrangement provides, in that particular case, the described feature of increased -- let me just find exactly the right point in the invention here -- you know, that arrangement increases the light-gathering ability.

So, you know, this Inokawa is an

Q. Well, we can get there in a moment. But let me just ask you about Figure 2 in Inokawa. And I'm not proposing that you change the lens or any of the structure in any way, other than to put the LED in the middle and detectors on the outside.

And my question to you is: Would a person of ordinary skill in the art have understood that even in that configuration the lens would still concentrate light towards the center, correct?

MR. SMITH: Objection; form.

A. So I think one of ordinary skill in the art would understand that a lens, in general, can provide concentration of light. The locations and directions of that concentration depend on the details of the design of the lens, the location of the sources, and the location at which you're interested in the presence or absence of concentration.

I think one of ordinary skill in the art would understand that in Inokawa the objective is to concentrate light at the detector, which is in the center axis of the drawing and that the lens is

capable of providing that benefit.

If we're going to move the lenses and the LEDs and detectors around and ask different questions, it's -- it isn't so obvious that Inokawa is specifically considering those scenarios. It's a little more hypothetical.

Q. I don't think that answers my question, to be quite honest with you. My question is Figure 2 in Inokawa, you testified that a person of ordinary skill in the art would look at that and understand that the lens combines the benefit of directing light towards the center detector. And I'm asking if, if the only thing you change in Figure 2 of Inokawa was to put the LED in the center and the detectors on the outside, wouldn't the lens still concentrate light towards the center?

MR. SMITH: Objection; form.

A. So in that arrangement, the lens does many things to different rays of light coming in from different directions, different reflection spots, different corpuscles for light along the axis coming into the lens. As I explained, the lens, that

power consumption and other features, but one of ordinary skill in the art would know how to maneuver within that, within that space.

Q. Okay. But your -- just to be clear, your Declarations don't discuss this process of adjusting sizes and shapes and locations that you've been -- that you referenced?

MR. SMITH: Objection to form.

A. That's correct. One of ordinary skill in the art would know how to do that.

Q. And so as I understand your testimony, convex lens may concentrate light in many different locations, correct? Is that, is that your testimony?

MR. SMITH: Objection; form.

A. Yes, I'd say depending on the location of the light, the orientation of the lens, the curvature of the index, the actual location that that light is deflected towards, it depends on all of those things and it could be many different locations.

Q. And does it depend on the location of

art would understand that it's within their skills and within the tools available to them to obtain benefits such as using refraction and concentration of the light to enhance the signal-to-noise ratio of the system.

Q. Is it your testimony that, you know, apart from extreme situations that a convex lens used over detectors and LEDs is always going to improve light concentration?

MR. SMITH: Objection; form.

A. Sorry to refer to extreme exception so that it would be plainly obvious that there would be no benefit without having to do any analysis. There are, there is a universe of possible designs here, some of which would provide benefits and some of which would not.

Q. So a convex lens may provide benefits in some situations and not others, depending on the location of the LEDs and the detectors; is that fair?

MR. SMITH: Objection to form.

A. And the shape of the lens and properties of the lens and a lot of other details.

As I said, there's a universe of possible design choices here. One of ordinary skill in the art would have the knowledge to make good choices and then follow that up with maybe some analysis or some experimental optimization in order to provide the benefits of, of improved pulse wave detection.

Q. In your Declaration, though, you don't describe any of those, any of that experimental optimization or other design choices. You take the lens of Inokawa and basically put that lens onto Aizawa, correct?

MR. SMITH: Objection; form.

A. So, no, I don't provide a sequence of procedure steps for doing any sort of optimization. I state plainly that a person of ordinary skill in the art would find it obvious to combine these elements and would know how to do so in a way that obtained and provided some benefit.

Q. Do you think the light-collection efficiency of a system is an important consideration for a person of ordinary skill in the art designing a noninvasive optical sensor?

A. I think what follows in the rest of that paragraph and the paragraph following that indicate that what we're looking for here is a transparent plastic material that is rigid and provides the other optical and mechanical characteristics that are important for this design of this system. Acrylic is one representative choice material, but it's not necessarily the only choice that one would use.

Q. And in your combination, is the, is the lens protrusion made of plastic at least? Can we agree on that?

MR. SMITH: Objection; form.

A. It could be plastic. It could be materials that you wouldn't necessary describe with that word. Could be glass. Could machine and polish a glass element. There's other materials one could use.

Q. Okay. So I just want to understand your opinions when you prepared this Declaration and you signed these Declarations. Your opinion is that a person of ordinary skill in the art would have been

led to a lens or protrusion but it could be made of a number of different materials. Is that, is that the testimony you're giving now?

MR. SMITH: Objection.

A. I think one of ordinary skill in the art would understand that you can obtain the benefits associated with Aizawa and Inokawa with materials, including acrylic and a number of other optical transparent plastics.

Q. So what other -- but what you just said is not in your report, correct, in your declaration?

MR. SMITH: Objection; form.

A. So we do on Paragraph 99 describe Nishikawa, another complementary reference.

Q. And in that paragraph you're discussing acrylic, correct?

A. Acrylic is a representative transparent plastic material that can be readily transformed into various shapes. I do not say it's the only such material one would ever use or consider using.

Q. Where do you say they were representative in Paragraph 99?

MR. SMITH: Objection; form.

Q. You don't, you don't the word "representative" in Paragraph 99.

Can we agree on that?

A. I think we can agree on that.

Q. Okay. What are you looking at now?

A. Just looking for other places where I describe the benefits of this combination, where I might have made some comments about the materials.

Reading in Aizawa Paragraph 13, this plate is described as a plate-like member. It doesn't explicitly require the use of acrylic.

Q. You're looking at Aizawa now. My question is about your Declaration, Dr. Kenny.

A. I know. This is the context for the choice of materials that one of ordinary skill in the art would consider for making the structure shown in the figure we've been referring to on page 55.

Q. So let me -- I just want to understand your opinions when you wrote this and

Q. If you're asking me what I'm asking about, I'm asking about your -- the basis for your assertion that the modification from the figure on the bottom left to the figure on the bottom right would increase light-gathering ability.

What, what is your basis for that assertion?

A. So the objective of this device is for light leaving the LED to enter the tissue, scatter off of some corpuscles or other blood carrying members, and be reflected towards the detectors and the objective is to improve the light-gathering efficiency of, of that arrangement by providing a convex lens where there's curvature of that lens positioned over the detector between the detector and where the reflection might be taking place.

I think one of ordinary skill in the art would understand that it's possible for a design of this type to provide improved light-gathering efficiency.

Q. You testified before that a convex

lens may have many locations where there's light concentration, correct?

A. That's correct.

Q. So where would the light collection locations be in your bottom figure right?

MR. SMITH: Objection; form.

A. So light reflecting off of corpuscles in the tissue nearby would be reflected back into the structure at many locations.

Q. Can you tell me where those locations are?

A. Well, I'll pick one. For example, the red detector on the right is one that I'm particularly interested in, in this design and there's the curvature of the lens that's provided over that location, would provide some enhanced light-collection efficiency because of the way of -- the refraction would, would change the pathways of the light in that region.

Q. Are there any other light -- are there other places where you opine that you believe there would be light --

MR. LARSON: Strike that.
Q. Are there other places where light collection would exist?
A. Sure, yes, maybe the detector on the left as well.
Q. Anywhere else?
A. It could be true at other locations in between.
Q. Can you tell me where those locations are?
A. At the location of the particular corpuscle and the various distances and angles but the, the general characteristic of a convex lens is that the refraction of that lens can provide some improved light-gathering efficiency.
Q. Can you tell me -- apart from the location of the detectors, can you tell me where these other alleged light-collection efficiency locations would be?
A. So it depends on the location of the reflected corpuscle or the corpuscle being reflected from, but imagining that there are many of them

increase in light concentration at the detectors relative to other areas?

MR. SMITH: Objection; form.

A. So if my goal was to have enhanced, you know, optimized light collection at a particular location, I would need to know the exact location of the reflecting corpuscles. In the absence of that precise knowledge, I think one of ordinary skill in the art would design a lens of this general shape, perhaps details as far as exact curvature and so on to be worked out, but this general shape to in general improve the light-collection efficiency at the location of the detectors.

Q. So you can't tell me looking at this figure, whether the light collection -- the increase in light-collection efficiency at the detectors would be greater than the alleged light-collection efficiency anywhere else; is that correct?

MR. SMITH: Objection; form.

A. It would depend on the details of the radius of curvature which is shown figuratively here but not in precise detail. It would depend on some

single focal point. It produces a, a sort of concentration over a region.

Q. What region?

A. It depends on the shape of the lens and the thickness of the less and other parameters, distance from the, the face of the lens to the locations of the detectors.

Q. How about the, the, the lens in your combination, the figure at the bottom right below Paragraph 97?

A. Yeah, I would say there's some, given the arrangement of the corpuscles as the reflecting objects in the space all around underneath that lens, that there would be some improvement in the light concentration at pretty much all of the locations under the curvature of the lens.

Q. And so when you said the convex shape results in a concentration over a region, your opinion is that the convex shape in your combination in the figure on the right below Paragraph 97 would increase light concentration at all the locations below the curvature of the lens; is that correct?

beam, perhaps as illustrated in some of the drawings in the '265 patent, lenses have different effects on parallel beams and point sources.

This is a scattered diffuse source of light and our objective here is to simply improve the percentage of that light that can be refracted toward the detectors. A convex lens provides that, that benefit.

Q. And, again, you don't have that analysis in your declaration, correct?

A. I think one of ordinary skill in the art working on these physiological sensors were monitoring these conditions would understand that you're dealing with a diffuse light source that's reflecting light back towards sensor and not a point source or a collimated light source.

Q. My question is just that analysis is not in your actual Expert Declarations, correct?

A. It's among the many things that I think were obvious to one of ordinary skill in the art.

Q. But not in your Declarations,

length. So the refractive effect will lead to a short mean of the path on average of the mean.

Q. So what you're showing here is that -- so when --

MR. LARSON: Sorry, strike that.

Q. So what you're discussing here when you say a mean path length, you're talking about the path on average; is that is that fair?

MR. SMITH: Objection; form.

A. So a mean path length mean the same as an average patent length, yeah.

Q. Is that how you're understanding it?

A. My understanding, yes, would be if I repeated this analysis for a multitude of path lengths, I would find that the majority of them would have a shorter path length.

Q. If you go down to Paragraph -- Paragraph 119, you say, "In more detail, I noted above for [1d] how the lens/protrusion of Inokawa, which is used to modify Aizawa's cover, provides a condensing function by refracting the light passing through it."

Q. And so with the convex shape in your combination, I think you testified just now that there would be a reduction in the amount of light at the perimeter and an increase as you come underneath the curvature towards the center; is that correct?

A. Maybe just to be precise, if you looked across -- if you looked on the example on the right and you had a way of measuring the light intensity from centered all the way to edge and you could do it for enough different examples of the corpuscle arrangements that you could average out those artifacts, you would see more light in the center than at the outer edge in this example.

Q. And that's because light's being directed towards the center and away from the edge, correct?

A. Among other things, yes, that's a part of why. Also, as we've discussed, this protruding lens is able to capture more light coming in at a weak angle that is additive to this effect.

Q. So it sounds like there's two considerations here. One is the convex lens in

general would direct more light to the center; the other is your testimony that a protruding lens overall would capture more light. Am I capturing your testimony correctly?

A. I think one of ordinary skill in the art would appreciate that those are both true, simultaneously, that you have the, the, the general lens-like shape of the convex lens provides refraction which allows additional concentration of light and light-collection efficiency, and that the protrusion provides an opportunity to capture some light that would otherwise not be captured.

Q. So just so we're clear, though, if you put aside your reasoning that the protrusion would otherwise provide an opportunity to capture more light that otherwise would be captured, the light that's being focused more towards the center is being directed away from the exterior, correct?

A. So the relative amounts of that -- of those two effects and the relative sizes of those effects, center of the edge, would depend on the details of the curvature design. You know, if we had

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.,	)	
	)	IPR NO. 2020-1520
Petitioner,	)	US PATENT NO: 10,258,265
-against-	)	IPR NO. 2020-1537
	)	US PATENT NO: 10,588,553
MASIMO CORPORATION,	)	
	)	IPR NO. 2020-1539
Patent Owner.	)	US PATENT NO: 10,588,554
	)	

VIDEO-RECORDED DEPOSITION OF

THOMAS WILLIAM KENNY, JR. PH.D.

VOLUME 2

Zoom Recorded Videoconference

04/23/2021

9:02 a.m. (PDT)

REPORTED BY: AMANDA GORRONO, CLR

CLR NO. 052005-01

DIGITAL EVIDENCE GROUP

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experiments. I could look in the library for reference materials. I could look for software. I'm just not sure what you're -- what "source" means in this, in this sentence, in this question.

Q. A journal article.

A. I'm sure there are journal articles that describe the effect of convex light sources on, on -- I'm sorry -- of diffuse light sources and optical systems.

Q. Can you name any?

A. Off the top of my head, no.

MR. SMITH: Objection; form.

Q. Do you cite any in your Declaration?

A. So most of the references in this Declaration are in the context of optical physiological sensors of the kind, perhaps, shown by the figures that we have in front of us here, where there's an object worn on a wrist or on some part of the anatomy. Light is directed into and detected on the way back out of the tissue.

I think most of those references and the authors and those relying on those materials

a person of ordinary skill in the art would -- who wants to apply the teaching of Inokawa, would consider the shape of the lens, the thickness index, curvature when applying Inokawa to a particular sensor configuration; is that fair?

A. Yeah. So, I mean, Inokawa is providing a concept of convex lens-like shape that makes it possible to increase the light-gathering ability. One of ordinary skill in the art would understand that, that what Inokawa provides is descriptive and not precise; that one shouldn't attempt to copy and paste the exact geometry of Inokawa into a different system and expect it would automatically be the right solution. One of ordinary skill in the art would do the work to improve the design in order to improve the opportunity for increased light collection efficiency. And --

Q. And so far I just want to be sure we're clear, you've discussed that a person of ordinary skill in the art would consider the shape of the lens, its thickness index curvature, the length, width and thickness of the lens.

Is there anything else that a person of ordinary skill in the art would consider when applying the teaching of Inokawa to a particular device?

A. Not that I can think of here. These are the routine parameters that would specify the shape of a lens that can be selected in order to obtain certain optical properties. This is straightforward for one of ordinary skill in the art.

Q. And you agree that Inokawa doesn't discuss the shape of the lens, its thickness index, curvature, the length, width and thickness of the lens, correct?

A. I don't believe that is precisely stated in Inokawa.

MR. SMITH: Objection to form.

Q. And you don't discuss any of those things in your Declarations, correct?

A. Precise numbers for any of those parameters, no. None of those are discussed.

I believe there are claims in one of the specifications that describe something related to

the art would include someone who has a Master of Science degree in, for example, mechanical engineering, but with no courses in -- no courses relating to physiology?

A. So, that student, for example, might have taken my Introduction to Sensors course, which as one part of the content covers a variety of sensors for different applications and we spend a solid portion of time looking at the Mendelson-1988 reference as an example of an optical physiological measuring system. They would have had that brief exposure to that particular instance.

And I can't speak to what other exposures they might have had in courses or projects or their other extracurricular activities.

Q. Focus here is trying to understand what experience and knowledge a person of ordinary skill in the art would definitely have, that would be required for that person to be considered a person of ordinary skill in the art.

And my question for you is whether a person with a Master of Science degree in, for

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC., Petitioner,
-against-
MASIMO CORPORATION, Patent Owner.

US PATENT NO: 10,588,553
IPR NO. 2020-1536

US PATENT NO: 10,588,554
IPR NO. 2020-1538

VIDEO-RECORDED DEPOSITION OF
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CLR NO. 052005-01

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Washington, D.C. 20036
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choice of the convex cover to a radially symmetric convex cover.

Q. What about the first picture under Paragraph 88 where you label a red circle that traces the edge of Mendelson '799 as a convex cover?

A. That is a convex cover.

Q. My question is: In this figure, you're illustrating the convex cover resulting from your combination of Mendelson '799 and Ohsaki as having a circular structure, correct?

MR. SMITH: Objection; form.

A. The top -- yes, the top view of the housing is circular and the convex cover is on top of the housing. I think that indicates that the cover is circular.

Q. Correct. And so I'm trying to see, was there an issue with my use of the term "radially symmetric convex cover"?

A. I'm comfortable with the word "circular." I think "radially symmetric" implies additionally symmetries beyond just the outer shape being circular.

Q. Can you describe to me the shape of the convex cover in your combination?

MR. SMITH: Objection; form.

A. It's a convex cover, the upper surface is convex.

Q. So we know that it's -- if you look at it from the top, it's circular, correct?

A. Yes.

Q. Okay. And we know that it's convex, correct?

A. That's correct.

Q. And so is it -- are you saying that it may not, it may not necessarily be symmetrically convex cover?

MR. SMITH: Objection; form.

A. That's what I'm saying.

Q. So it could be an asymmetrical convex cover?

A. Or maybe not a perfect convex symmetric, you know, spherically or circularly symmetric shape. It doesn't necessarily need that kind of perfection.

within the scope of a protruding convex cover.

Q. So a person of ordinary skill in the art combining Ohsaki and Mendelson '799 would address a number of detailed choices regarding performance, cost, size, shape and other parameters to obtain a variety of structures for the convex cover; is that your testimony?

MR. SMITH: Objection; form.

A. I don't think that's exactly what I said unless you're reading it back, I think, but the meaning is similar. One of ordinary skill in the art would consider the shape of the cover, along with other design elements, including manufacturability costs, power consumption. I can make a long list of things that would be considered in the process of completing a final detailed design of, of such a product. And the protruding convex cover would be a, would be part of that final product.

Q. And the only thing you can tell me about the three-dimensional structure of the cover that would result from that process is that it would be a protruding convex cover, correct?

MR. SMITH: Objection; form.

A. I don't think I need -- I don't think it is necessary to add any other specific narrowing description in this case.

Q. And just so I'm clear, does the term "protruding convex cover" specify to you any three-dimensional geometry that you can explain to me, beyond the use of that phrase?

MR. SMITH: Objection; form.

A. I don't think it's necessary to narrow that description. I think one of ordinary skill in the art might arrive at a final shape that is more generic than any of the particular narrowing descriptions I might apply at this time.

You know, for example, you started off with the term "radially symmetric" and I think I was -- in this context circular, I think makes sense, given the circular shape of the housing in Mendelson '799, but radially symmetric is not a required limitation in order to achieve the benefits that one would be motivated to achieve.

Q. Okay. So the -- focusing on a

When you wrote your Declarations, did you have in mind a specific three-dimensional structure for the cover that is in your combination of Ohsaki and Mendelson '799?

MR. SMITH: Objection; form, asked and answered.

A. Ohsaki provides an example of a transparent protruding convex cover that is intended to improve adhesion between the sensors -- between the sensor and the user's tissue and to provide detection efficiency and provide additional protection of the elements accommodated within the housing. I think one of ordinary skill in the art would understand how to design a transparent protruding convex cover as described by Ohsaki so as to achieve those benefits in combination with the elements in Mendelson '799.

Q. Well, can you answer my question now? My question is: When you wrote your Declaration -- the factual question, Dr. Kenny, when you wrote your Declarations, did you have in mind a specific three-dimensional structure for the cover that's in

your combination of Ohsaki and Mendelson '799?

A. A specific --

MR. SMITH: Objection; form, asked and answered.

A. So you're talking about a specific shape --

Q. Yes.

A. -- size, curvature, all of the dimensions, something out of a lens handbook, for example? I did not. I think one of ordinary skill in the art would understand that the choices of the details of the size, shape, thickness, radius, curvature, other parameters, would be dependent on other -- the way the element worked with the rest of design and would know how to proceed forward in making those determinations and choices.

MR. SMITH: Hey, Stephen, we've been going for a little more than an hour. It might be a good time for a break if you come to the end of this line of this questioning.

MR. LARSON: I'm not sure if there is a good -- yeah, I hear you. We'll try to take a

Ohsaki and Mendelson '799, correct?

A. That's my opinion, one of ordinary skill in the art would know how to carry that out.

Q. But you didn't put the, the result of -- you didn't, you didn't identify a specific structure that would result from that analysis in your Declarations, correct?

MR. SMITH: Objection; form.

A. That's correct, my Declaration doesn't go all the way to producing a complete final design of a specific structure with dimensions and parameters all chosen. My Declaration offers the opinion that one of ordinary skill in the art would now how to combine the features and be motivated to do so in order to improve adhesion, improve detection efficiency and provide additional protection for the elements accommodated within the sensor housing.

Q. Now, you're -- do you consider yourself a person of skill in the art?

A. Yes.

Q. So you could have done that analysis and provided the result of that analysis in your

Declaration, Declarations, correct?

MR. SMITH: Objection; form.

A. In the context of a specific design, yes.

Q. Correct.

A. Yes, I believe so.

Q. Okay. But you didn't believe that was necessary in your Declarations?

MR. SMITH: Objection; form.

A. That's correct. I believe one of ordinary skill would know how to make those determinations --

Q. And --

A. -- depending on the circumstances. In other words, going around in circles, I know.

Q. Well, please let me show -- finish your answer. I thought you were done talking.

A. I'm sorry. One of ordinary skill in the art would understand how to make those determinations in the context of combining the details of a particular design.

MR. LARSON: Okay. Let's -- is it a

within the package.

Q. What is a translucent member?

MR. SMITH: Objection; form.

A. I understand translucent in the context of Ohsaki to mean -- let's see exactly where he uses the phrase --

The translucence is the property that allows the light through the emitter to propagate through the member, be reflected off of some element of the tissue and then be able to propagate back through the member to the detector. It allows light to pass.

Q. Okay. I think you explained your understanding of translucent. What about member?

A. Member is an object.

Q. Do you describe any particular three-dimensional shape to a member?

MR. SMITH: Objection to form.

A. No, it's an object.

Q. Okay. Now, Ohsaki has some illustrations that are cross-sectional views of Ohsaki's cover, correct?

A. That is correct.

Q. Do you have an understanding of what the three-dimensional structure of Ohsaki's cover is based on those illustrations?

MR. SMITH: Objection; form.

Q. Based on those illustrations -- yeah.

Do you have an understanding of the three-dimensional structure of Ohsaki's cover based on those illustrations and Ohsaki as a whole?

MR. SMITH: Same objection.

Q. For --

A. Ohsaki does not provide a top view, either in Figure 1 or Figure 2. And there's, at least to my knowledge, there's nothing in the text that describes the shape from the top.

Q. Okay. So can you explain your understanding in the three-dimensional structure of Ohsaki's cover?

MR. SMITH: Objection; form. Asked and answered.

A. So Ohsaki describes the pulse -- this is Paragraph 16 in Ohsaki -- describes the pulse wave

sensor as being worn on the back side of the user's wrist, corresponding to the back of the user's hand in a similar manner as a wristwatch is normally worn.

Q. My question is focused on the cover of Ohsaki, correct? You understand that?

A. Yes, I have a cross-sectional view. I don't have a top view that would allow me to assert that the shape was necessarily circular or square or rectangular. Ohsaki does not limit to a particular shape from the top, that I'm aware of.

Q. Okay. But when you combined Ohsaki's cover with Mendelson '799, did you have a particular shape of Ohsaki's cover in mind?

MR. SMITH: Objection to form.

A. I have the shape of the housing of Mendelson in mind, which is circular, clearly indicated; and that the convex cover that I would arrive at, inspired by Ohsaki, would be circular in order to accommodate the shape of the housing of Mendelson.

Q. So you used the structure of Mendelson '799 to guide the shape of the cover that

would provide a system that included the benefits of improved adhesion and detection and protection of the elements inside the, the product.

Q. Does Ohsaki provide any guidance as to how the board could, should or should not be changed --

MR. LARSON: Let me restate that.

Q. Does Ohsaki provide any guidance as to how the board should or should not be changed to maintain adhesion?

A. So Ohsaki does not provide a detailed, precise, geometrically specific description of the board. It's illustrated in Figures 1 and 2, and one of ordinary skill in the art would understand how to select a particular shape with a convex surface so as to obtain improved adhesion and, and detection. Ohsaki does not provide a detailed specification of the lens shape.

Q. Where does Ohsaki provide that guidance that you just described?

MR. SMITH: Objection; form.

A. You're asking me where does Ohsaki

Q. The question is as follows: You described Paragraph 19 as describing "one portion of a description of a preferred embodiment."

Is there another embodiment described by Ohsaki?

MR. SMITH: Objection; form.

A. So I -- the summary of the invention describes features and benefits of the addition of a translucent member with a convex surface to an element attached on the user's wrist. The particular embodiment shown in Figures 1 -- well, Figures 2 -- Figures 1 and 2 represent a particular example of how to incorporate the invention in the context of a specific watch design.

Q. He only describes the structure of one embodiment; is that fair?

A. So --

MR. SMITH: Objection; form.

A. -- very little precise description of the structure of the embodiment. It doesn't ever state dimensions, thicknesses, things like that. My interpretation of this is that this particular

description is an example of an embodiment that, that, that Ohsaki is providing to explain the idea of the benefits of a convex cover applied to the back side of a watch, which would be to improve adhesion and to improve detection.

Q. Now, you said -- you testified that one of ordinary skill in the art would consider Paragraph 19 and make a decision as to how it might influence their decisions in deciding a combination of translucent member with a convex surface and the sensor elements of Mendelson '799.

How did you consider Paragraph 19 in putting together a combination that you, you put together in your, your Declarations?

MR. SMITH: Objection; form.

Q. Do you remember?

MR. SMITH: Objection; form.

Q. For the record, are you looking at your Declaration?

A. I'm looking at Paragraph 19.

Q. Oh, okay. You're looking at Paragraph 19 of Ohsaki?

ordinary skill in the art, as modifying concepts from sources to build a real device.
Q. Okay. But you can't point me to anything else in Ohsaki that specifically discusses what the shape of the, of the board should be, correct?
A. There's no explicit statements --
MR. SMITH: Objection; form.
A. -- about the shape of the elements of Ohsaki.
MR. SMITH: Stephen, when you come to the end of the line of questioning, we're coming up on noon, Pacific, you might want to take a break.
Q. So you understand that a person of ordinary skill in the art is a hypothetical person, it's one person, correct?
MR. SMITH: Objection; form. Argumentative.
A. I think of my description of a person of ordinary skill in the art is representing a broad class of humans that can perform these tasks. I'm not thinking of a particular person that I know. If

properly, arranged on the user's wrist -- just -- context...

It's really not clear that all four cases are described in rank here. So there's two orientations of the Detecting Element 2, right, and there's the possibility of a convex surface or a flat surface. I think the Paragraph 25 makes it clear that if the element has a flat surface, the detected pulse wave is adversely affected by movement and I take that to mean that would be the case regardless of the orientation of the body, but I'm interpreting. It's not literally stated.

Q. And you can't interpret Paragraph 25 without also considering Paragraph 19, correct?

A. Correct. And so Paragraph 19 --

MR. SMITH: Objection; form.

A. -- tells me that in one orientation there is a tendency to slip. That doesn't tell me whether that tendency is worse or better than the case of a flat surface.

Q. Yeah. Ohsaki doesn't discuss that specific question; is that true?

MR. SMITH: Objection; form.

A. It doesn't. So Ohsaki doesn't have the additional paragraphs that might have described the orientation of all of those elements in more detail. That's correct. All -- what I know here is that Ohsaki is specific about the two possible orientations of the element, Number 2, the entire structure.

If, if one dimension is longer than the other, there's then two choices and that it has convex cover, a cover with a convex surface, that's in contact with the skin.

But, you know, from all of this, I -- there's nothing that tells me anything in particular about the shape or dimensions of the cover, this translucent convex cover.

Q. At the very least, a person of skill in the art would have understood that Ohsaki's convex member did not prevent slipping when the sensor was placed in the circumferential direction of the user's wrist, correct?

MR. SMITH: Objection; argumentative,

with the palm of the hand (indicating).

Q. Okay. And so some of your previous testimony, you had those switched?

A. That's correct. In the last section, I was partly talking about Paragraph 24 and the relationship of the bones to whether or not a person would be comfortable or not, so I, I got myself kind of wound into a rabbit hole there. Let's, if we could, please consider that some of that testimony was using front and back, in a mixed-up way, so we can get back on track now. The back of the hand and the back of the wrist are on the same side.

So Figure 3(a) is related to a measurement of the sensor mounted on the back of the wrist where we would normally wear a watch. And 4A show a sensor with a convex protrusion as compared with a sensor element that has a flat cover.

Q. And do you have an understanding of, of where the device is being -- on which side the sensor is in Figure 4?

A. I think most of the specification is referring to the sensor mounted on the back of the

wrist, so I'm -- it doesn't say explicitly, but I'm going to make that judgment. I think one of ordinary skill in the art would think Figure 4 applies to a sensor mounted on the back of the wrist.

Q. Okay. So a few moments ago, before we went to the break, you testified you believe the performance shown in Figure 3 and 4A were comparable. And my question for you is: Does that help you understand whether Figure 3A tested a device with a convex surface?

MR. SMITH: Objection; form.

Q. Does that help you understand that Figure 3A tested a sensor with a convex surface?

MR. SMITH: Same objection.

A. Back side of user's wrist -- I think that's the most reasonable interpretation. It's not clearly stated in Paragraph 24, which describes Figure 3A, but in the context of the specification, I believe that the element being tested in Figure 3(a) and 3B has a convex cover, and what's being illustrated is that it's better to mount the sensor on the back of the wrist than on the front of the

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	Poeze, et al.	
U.S. Patent No.:	10,258,265	Attorney Docket No.: 50095-0006IP1
Issue Date:	April 16, 2019	
Appl. Serial No.:	16/212,440	
Filing Date:	December 6, 2018	
Title:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS	

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Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION FOR *INTER PARTES* REVIEW OF UNITED STATES PATENT NO. 10,258,265 PURSUANT TO 35 U.S.C. §§ 311–319, 37 C.F.R. § 42

Masimo Ex. 2019
Apple v. Masimo
IPR2020-01713

APPLE-1006, FIG. 1(b) (modified); APPLE-1003, ¶116.

<u>Claim 11</u>

[11]: "The noninvasive optical physiological measurement device of claim 10, wherein the light permeable cover is configured to act as a tissue shaper and conform tissue of the user to at least a portion of an external surface shape of the light permeable cover when the noninvasive optical physiological measurement device is worn by the user."

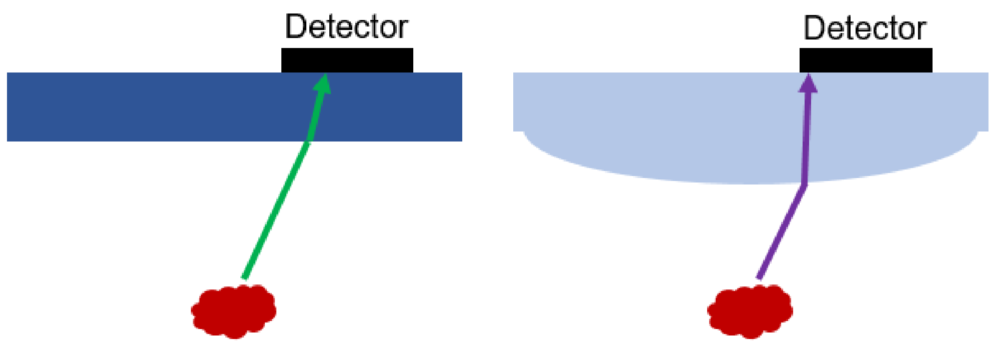
Aizawa-Inokawa renders obvious [11]. *Supra* Ground-1A [10]; APPLE-1003, ¶117. As explained for [10], the light permeable cover of Aizawa-Inokawa deforms the tissue around the lens/protrusion when pressed against the wrist of the user. APPLE-1003, ¶117. Thus, the light permeable cover shapes the tissue around its external surface when the device is worn. *Id.*

<u>Claim 12</u>

[12]: "The noninvasive optical physiological measurement device of claim 11, wherein the light permeable cover is configured to reduce a mean path length of light traveling to the at least four detectors."

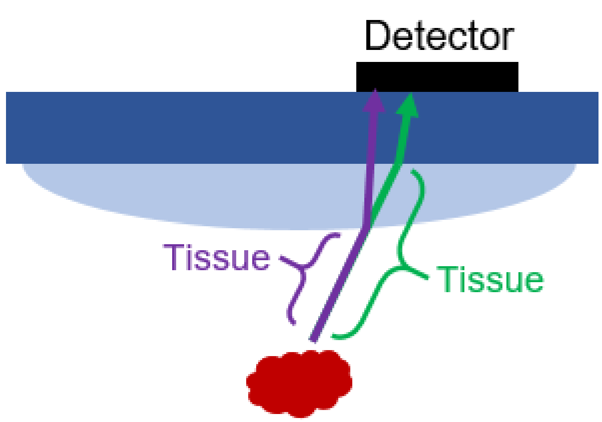
A POSITA would have recognized that such feature is rendered obvious by Aizawa-Inokawa. APPLE-1003, ¶118. For example, the lens/protrusion of Inokawa, which is used to modify Aizawa as explained in Section III.A.3(a), serves a condensing function and thus, as with any other lens, refracts light passing through it. APPLE-1008, [0015], [0058]; APPLE-1003, ¶119. Thus, referring to the drawing below which compares the length of non-refracted light (*i.e.*, without a lens, left) bouncing off an artery with that of refracted light (*i.e.*, with a lens, right),

it can be seen that the mean path length of light traveling to the at least four detectors is reduced—that is, the purple line is shorter than the redline. APPLE-1003, ¶119. This holds true for both the total length travelled as well as length travelled/attenuated through skin. *Id.*



APPLE-1003, ¶119.

Superimposing the two drawings above clearly shows the shortened path traveled by refracted light in the presence of a protrusion/lens, both within the tissue as well as for total path length:



APPLE-1003, ¶120.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	Poeze et al.
U.S. Patent No.:	10,258,265 Attorney Docket No.: 50095-00006IP1
Issue Date:	April 16, 2019
Appl. Serial No.:	16/212,440
Filing Date:	December 6, 2018
Title:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS

DECLARATION OF DR. THOMAS W. KENNY

Declaration

I declare that all statements made herein on my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable under Section 1001 of Title 18 of the United States Code.

By: ______________________

Thomas W. Kenny, Ph.D.

Masimo Ex. 2020
Apple v. Masimo
IPR2020-01713

lens/protrusion during use. APPLE-1006, [0006], [0026]; APPLE-1008, FIG. 2. In this way, the lens/protrusion acts as a tissue shaper that helps conform the tissue of the user to an external surface of the lens/protrusion when the device is worn by the user. *Id.* As explained for [10], this happens because a protruded surface that is more rigid than the skin is being pressed into the skin and, accordingly, the less rigid skin will at least partially deform to conform to the rigid protrusion. *Id.*

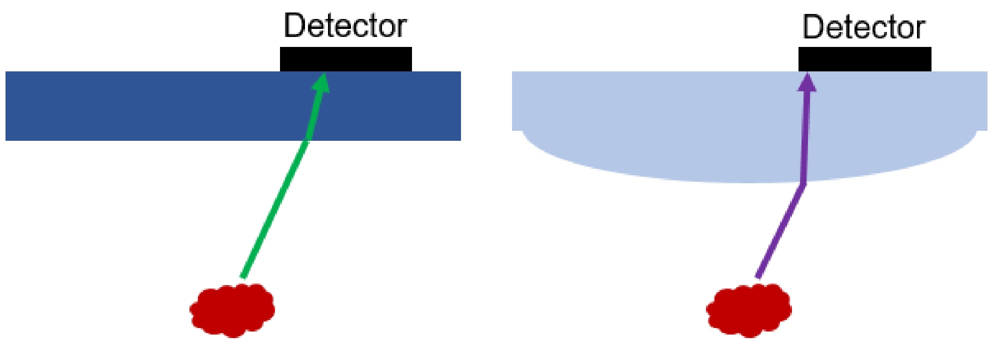
K. Claim 12

[12] The noninvasive optical physiological measurement device of claim 11, wherein the light permeable cover is configured to reduce a mean path length of light traveling to the at least four detectors.

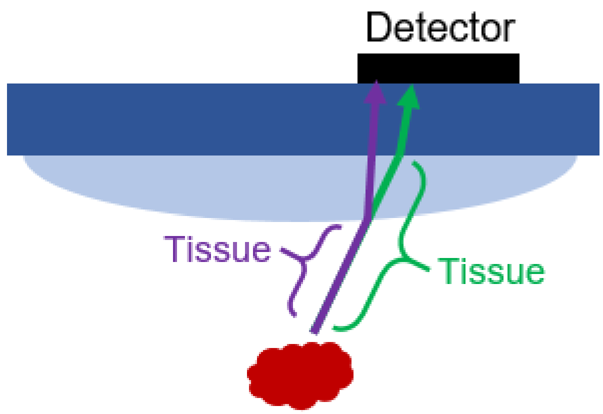
118. Regarding the reduction of mean path length, the ’265 patent mentions, in the context of a transmittance-type device, that using a protruded cover to deform the skin can cause “the mean optical path length from the emitters to the detectors can be reduced and the accuracy of blood analyte measurement can increase.” APPLE-1001, 20:25-20, FIG. 5. Although the ’265 patent is silent regarding how such path reduction would apply in a reflectance-type sensor, a POSITA still would have recognized that an analogous effect can be achieved the Aizawa-Inokawa combination.

119. In more detail, I noted above for [1d] how the lens/protrusion of Inokawa, which is used to modify Aizawa’s cover, provides a condensing function by refracting the light passing through it. APPLE-1008, [0015], [0058]. As

demonstrated through my drawings below, where the left figure shows the length of non-refracted light and the right figure shows the length of refracted light, such refraction of the incoming reflected light can shorten the path of the light before it reaches the detector. This is because the incoming light is "condensed" toward the center. APPLE-1008, [0015], [0058]. Thus, as demonstrated by the drawings below, both the total length of travel as well as the length through the tissue can be reduced.



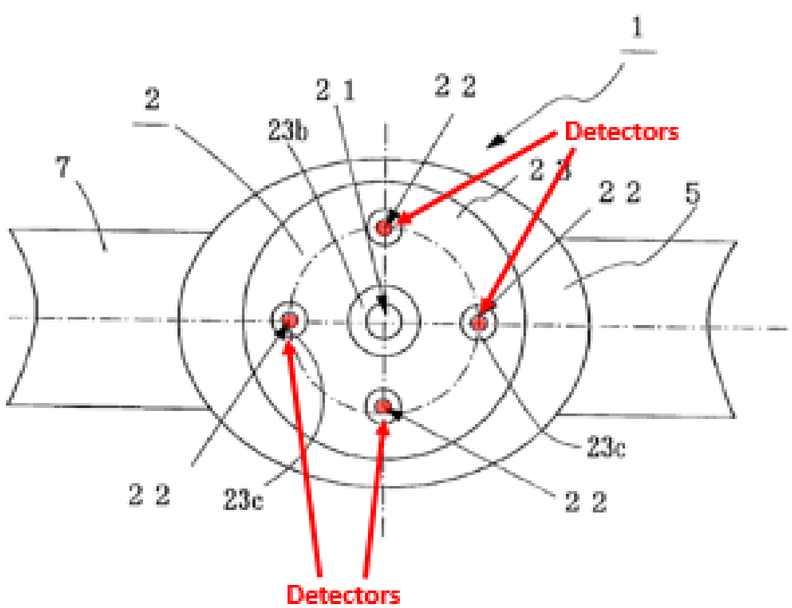
120. Laying these two drawings on top of each other, as shown below, the shortened path length within the tissue for the purple (refracted) line can be clearly seen compared to the path length within the tissue of the green (non-refracted) line. The shortened *total* path length of the purple line compared to the green line can also be seen. Accordingly, the Aizawa-Inokawa combination, through its use of a condensing lens between the tissue and the detectors, serves to reduce a mean path length of light traveling to the at least four detectors



L. Claim 13

[13] The noninvasive optical physiological measurement device of claim 11, wherein the at least four detectors are evenly spaced from one another.

121. As explained above with respect to [c], Aizawa teaches at least for detectors. APPLE-1006, [0029], [0024], [0032], FIG. 1(a). Further, as shown below, the four detectors are evenly spaced from one another. *Id.*



APPLE-1006, FIG. 1(a)

M. Claim 14

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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APPLE, INC., Case IPR2020-01520

U.S. Patent 10,258,265

Petitioner,

Case IPR2020-01539

U.S. Patent 10,588,554

-against- Case IPR2020-01537

U.S. Patent 10,588,553

MASIMO CORPORATION, Case IPR2020-01536

U.S. Patent 10,588,553

Patent Owner.

Case IPR2020-01538

U.S. Patent 10,588,554

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VIDEO-RECORDED DEPOSITION OF

THOMAS WILLIAM KENNY JR., PH.D.

Zoom Recorded Videoconference

09/18/2021

9:03 a.m. Pacific Daylight Time

REPORTED BY: AMANDA GORRONO, CLR

CLR NO. 052005-01

DIGITAL EVIDENCE GROUP

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Masimo Ex. 2027
Apple v. Masimo
IPR2020-01713

correct?

A. That's correct.

Q. The indication in this figure, "Toward the center," does that indicate the redirection that leads to the detector capturing light that otherwise would have been missed --

MR. SMITH: Objection; form.

Q. -- for a particular ray?

MR. SMITH: Same objection.

A. So just again, reading from Paragraph 42, the "lens' ability to direct light 'toward the center' would allow the detector to capture light that would otherwise have been missed by the detectors, regardless of their location within the sensor device."

Q. So there, there is some light that would have been captured by the detectors that is redirected and no longer hits the detectors; is that correct?

MR. SMITH: Objection; form.

A. So of all of the photons scattered backwards from all of these sites --

Q. Correct.

A. -- and interacting with this curved optical surface that we're calling the lens, some of those rays are diff- -- sorry -- refracted in a way that directs them toward the detectors which otherwise might have missed, and there would be some other rays that would have hit the detectors that are refracted away from the detectors; that's correct.

Q. So in your analysis, did you determine the relative amount of light that is refracted towards the detectors that would otherwise have been missed and compare it to the amount of light originally going to the detector that is now refracted away and misses the detector, with the presence of the convex surface?

MR. SMITH: Objection; form.

A. In order to perform such an analysis, I would need to know a full set of detailed dimensions and shapes of the objects that would be involved in that final design. So there was no such detailed calculation presented for this cartoon representation of the combination of elements from

the references.

What I've stated throughout the earlier Declaration and throughout the earlier deposition is that a person of ordinary skill in the art would understand how to take advantage of the detector locations and the shape of this convex surface so as to obtain an improvement in the amount of light arriving at the detectors.

Q. The improvement in the light arriving at the detectors depends on the dimensions and shapes of the objects in the final design; is that correct?

MR. SMITH: Objection; form.

A. Yes, yes.

Q. And in this Declaration, there was no detailed calculation presented for dimensions and shapes that establish that relatively more light reaches the detectors for a convex surface than for a flat or no surface; is that correct?

MR. SMITH: Objection; form.

A. So we could read from Paragraph 44, "As I made clear during my deposition," and following that is a quote, I think, from the transcript of the

Q. I don't think that that reference, I, I may be wrong, but I don't think that reference was part of these proceedings, but I want to direct you to part of Mendelson 1988 which I think you've cited in, in these proceedings and maybe all of the proceedings we've talked about today -- we're going to talk about today, okay?

A. Uh-huh.

Q. Page 2 of the reference in the left-hand column?

A. Uh-huh.

Q. Final paragraph in that column?

A. Uh-huh.

Q. "The intensity of the backscattered light decreases," do you see that sentence?

A. Yes.

Q. So for a sensor with a central emitter and peripheral detectors, the intensity of the light decreases with the square of the distance; is that correct?

A. That's what this reference says.

Q. And is that your understanding

generally of physiological sensors that use a central emitter and peripheral detectors?

A. I think there's other references from the same authors that use the word "exponential decrease or rapid decrease." And the data I remember seeing is, I think, more or less consistent with all of those descriptions without precisely fitting to a particular analytic dependance between distance and signal. So I think the general understanding that all of these references would agree with is that there is a decrease in the light as you move away from the location of the emitter towards the perimeter of the sensor.

Q. The decrease in the backscattered light, when you -- based upon this disclosure, when you go from 1 millimeter to 2 millimeters, the intensity will be 25 percent of what it was 1 to 2; is that, is that correct? Am I understanding that correct? If you double --

MR. SMITH: Objection; form.

Q. -- if you double your distance?

MR. SMITH: Objection; form.

BY MR. HELM:

Q. Dr. Kenny, before the break, we were talking about Mendelson 1988. I want to go back to the disclosure about the intensity of the light -- of the backscattered light decreases in proportion -- direct proportion of the square of the distance. That is Page 2 of Mendelson 1988, bottom of the first column on the left.

A. That's -- yes.

Q. So based on that disclosure, if the intensity of the light decreases with the square of the distance, doubling the distance results in a 4-fold decrease in the amount of light; is that correct?

MR. SMITH: Objection; form.

A. If we're considering exactly the same detector just repositioned a factor or two further away, then if as stated, it's -- the light decreases in proportional of the square of the distance, then that displacement by a factor of two in distance would correspond to a factor of four reduction in the signal for that detector.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	Poeze, et al.
U.S. Patent No.:	10,702,194
Issue Date:	July 7, 2020
Appl. Serial No.:	16/829,536
Filing Date:	March 25, 2020
Title:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS

Attorney Docket No.: 50095-0025IP1

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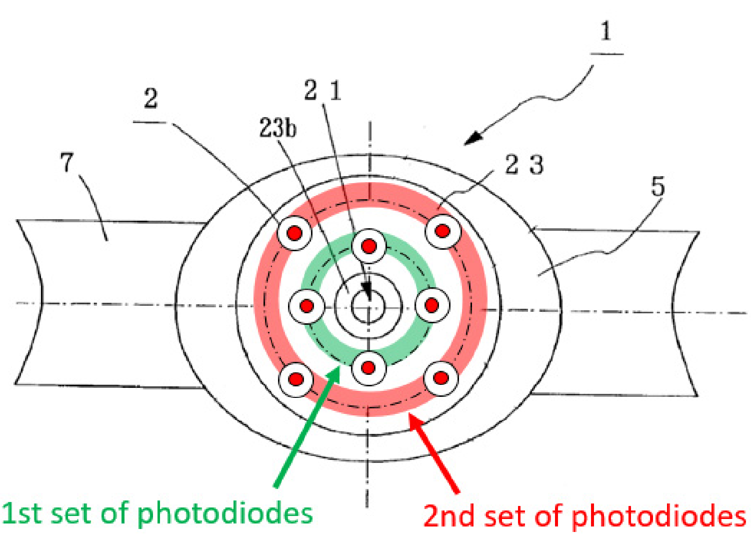
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION FOR *INTER PARTES* REVIEW OF UNITED STATES PATENT NO. 10,702,194 PURSUANT TO 35 U.S.C. §§ 311–319, 37 C.F.R. § 42

positioned) of photodiodes as a desirable detector configuration that would reap similar benefits for Aizawa in terms of achieving "power savings in the design of a more efficient" pulse sensing device. APPLE-1024, 3017; APPLE-1003, ¶71. Indeed, by using Mendelson-2003's power-saving (and thus efficiency-enhancing) PD configuration, the power consumption of a wrist-based pulse sensing device as in Aizawa can be reduced through use of a less bright and, hence, lower power-consuming LED. APPLE-1003, ¶71. This, of course, would allow Aizawa's wrist-based device to enjoy a longer battery life. *Id.*

An example implementation of adding an additional ring of detectors to Aizawa, as per Mendelson-2003, is illustrated below:



APPLE-1006, FIG. 1(a); APPLE-1003, ¶72.

A POSITA would further recognize, in view of Mendelson-2003, that such a two-ring arrangement can be implemented in a wrist sensor device as in Aizawa by wiring each ring of detectors in parallel and summing the input of their respective streams. APPLE-1024, 3017; APPLE-1003, ¶73 (citing APPLE-1042, 5:20-67, FIGS 1-2; APPLE-1025, 4:23-30).

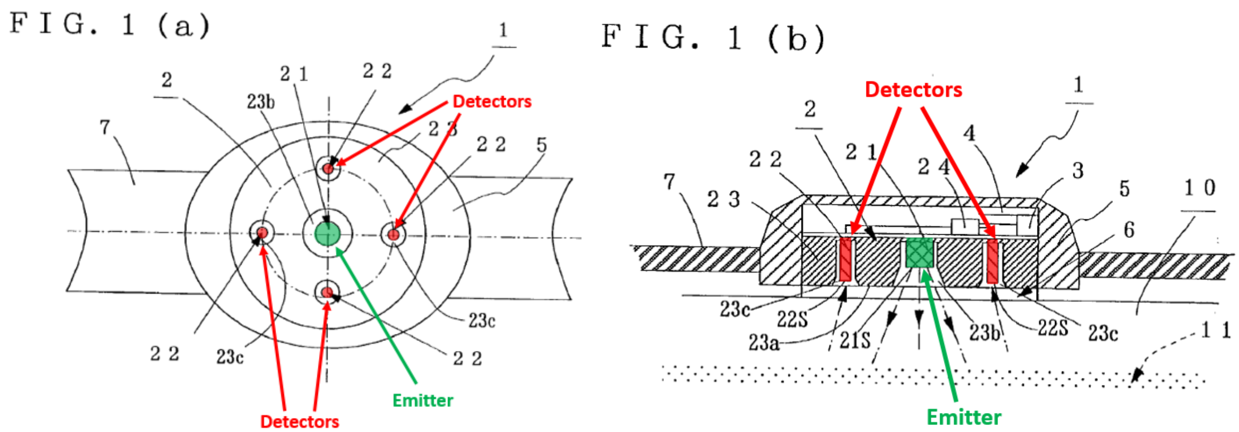
A POSITA also would have found it obvious to modify Aizawa with Mendelson-2003 to add an additional ring of detectors because doing so merely entails the use of known solutions to improve similar systems and methods in the same way. APPLE-1003, ¶74. Indeed, "when a patent 'simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007). A POSITA would have recognized that applying Mendelson-2003's teachings regarding two, concentric rings of detectors that are each connected in parallel to Aizawa's sensor would have led to predictable results without significantly altering or hindering the functions performed by Aizawa's sensor. APPLE-1003, ¶74. A POSITA would have been motivated to provide the well-known feature of providing multiple rings of emitters to a pulse sensor to achieve the predictable benefits offered by Mendelson-2003's description of the same. *Id.*. In fact, Aizawa itself contemplates the addition of extra detectors to improve light collection efficiency, although it does

not disclose whether they may be arranged as two concentric rings. APPLE-1006, [0032]; APPLE-1003, ¶74. Moreover, as noted above, Mendelson-2003 expressly contemplates adding an additional ring of detectors to a conventional 1-ring PD arrangement precisely as found in Aizawa. APPLE-1024, 3016; APPLE-1003, ¶74.

Cover comprising a protruding convex surface

Additionally, a POSITA would have combined the teachings of Aizawa-Mendelson-2003 with the teachings of Ohsaki such that the cover of Aizawa-Mendelson-2003's wrist-worn sensor would include a convex surface, improving adhesion between a subject's wrist and a surface of the sensor. APPLE-1014, [0025] (the convex surface prevents slippage of the detecting element from its position on the subject's wrist, and the convex nature of the surface suppresses the "variation of the amount of the reflected light" that reaches the detecting element); APPLE-1003, ¶¶75-83.

In more detail, Ohsaki describes a "detecting element" that includes "a package 5, a light emitting element 6 (e.g., LED), a light receiving element 7 (e.g., PD), and a translucent board 8." APPLE-1014, [0017]. "The package 5 has an opening and includes a" substrate in the form of "circuit board 9," on which light emitting element 6 and light receiving element 7 are arranged. *Id.*; APPLE-1003, ¶76. As shown in Ohsaki's FIG. 2, translucent board 8 is arranged such that, when the sensor is worn "on the user's wrist … the convex surface of the translucent board … is

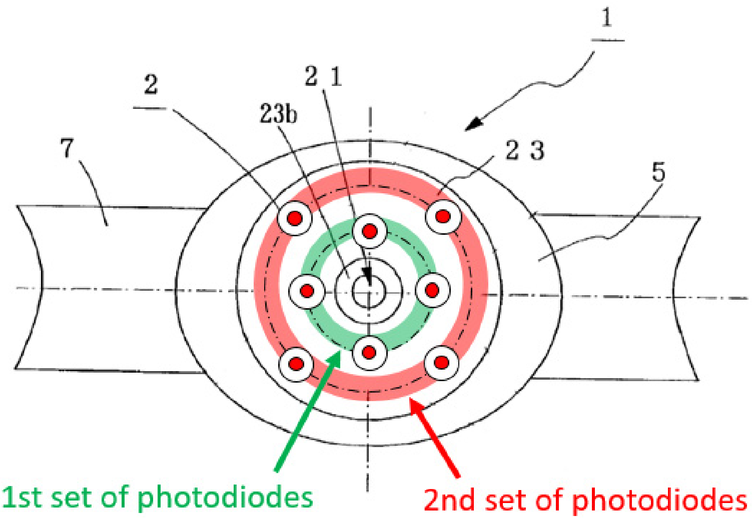


APPLE-1006, FIGS. 1(a)-1(b).

[1c]: a first set of photodiodes, wherein:

[1d]: the first set of photodiodes comprises at least four photodiodes,

The Aizawa-Mendelson-2003-Ohsaki-Mendelson-2006 combination renders obvious elements [1c] and [1d]. APPLE-1003, ¶¶90-91 Indeed, as discussed above in Section III.A.5 and shown below, a POSITA would have been motivated, in view of Mendelson-2003, to provide an additional ring of photodiodes/detectors to Aizawa in order to, among other things, "widen[]the active area of the PD" and thereby "collect a bigger portion of backscattered light intensity." APPLE-1024, 3019; APPLE-1003, ¶90. As noted above, the resulting widening of the detection area would result in "power savings achieved by widening the overall active area of the PD" as the detectors will be able to more efficiently detect the reflected light coming from the LED (and thus the LED will be able to operate at reduced power). APPLE-1003, ¶90.



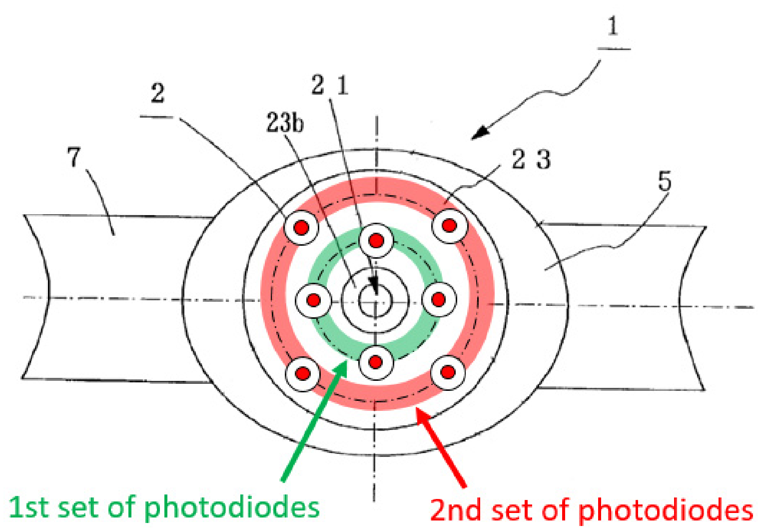
APPLE-1006, FIG. 1(a).

In the modified device shown above, where an additional ring of detectors has been added to Aizawa to form two concentric rings as discussed above in Section III.A.5, the inner ring of photodiodes (shown in green) can be equated to the claimed first set of photodiodes and includes at least four photodiodes. APPLE-1006, [0032], FIG. 1(a), FIG. 4(a); APPLE-1003, ¶91.

[1e]: the photodiodes of the first set of photodiodes are connected to one another in parallel to provide a first signal stream, and

As discussed above in Section III.A.5, Aizawa-Mendelson-2003-Ohsaki-Mendelson-2006 renders obvious first and second sets of photodiodes. As detailed below, POSITA would have recognized and/or found it obvious that the first set of

The Aizawa-Mendelson-2003-Ohsaki-Mendelson-2006 combination renders obvious elements [1g] and [1h]. APPLE-1003, ¶¶100-101. Indeed, as discussed above in Section III.A.5 and shown below, a POSITA would have been motivated, in view of Mendelson-2003, to provide Aizawa's multiple detectors in two concentric rings in order to, among other things, "widen[]the active area of the PD" and thereby "collect a bigger portion of backscattered light intensity." APPLE-1024, 3019; APPLE-1003, ¶100. This effective widening of the detection are would result in "power savings achieved by widening the overall active area of the PD" as the detectors will be able to more efficiently detect the reflected light coming from the LED. APPLE-1003, ¶100.



APPLE-1006, FIG. 1(a).

In the modified device shown above, where an additional ring of detectors has been added to Aizawa to form two concentric rings as discussed above in Section III.A.5, the outer ring of photodiodes (shown in red) can be equated to the claimed second set of photodiodes and includes at least four photodiodes. APPLE-1006, [0032], FIG. 1(a), FIG. 4(a); APPLE-1003, ¶101.

[1i]: the photodiodes of the second set of photodiodes are connected to one another in parallel to provide a second signal stream, and

For reasons discussed above for element [1e], the analysis for which is fully incorporated herein, a POSITA would have found it obvious that the photodiodes in the second/outer ring (*i.e.*, second set of photodiodes) in Aizawa's modified device are connected to one another in parallel to provide a second signal stream. APPLE-1003, ¶102.

[1j]: each of the photodiodes of the second set of photodiodes has a corresponding window that allows light to pass through to the photodiode;

The Aizawa-Mendelson-2003-Ohsaki-Mendelson-2006 combination renders obvious [1j]. *Supra* [1f]; APPLE-1003, ¶103. In particular, each photodiode in modified Aizawa's second set of photodiodes would have included a corresponding window to further enhance light collection efficiency. APPLE-1006, [0024], [0012], FIG. 1(b); APPLE-1003, ¶103.

[1k]: a wall that surrounds at least the first and second sets of photodiodes; and

Filed August 6, 2021

On behalf of:
Patent Owner Masimo Corporation
By: Joseph R. Re (Reg. No. 31,291)
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.
Petitioner,

v.

MASIMO CORPORATION,
Patent Owner.

IPR2020-01716
Patent 10,702,194

PATENT OWNER RESPONSE

1. **Petitioner's Proposed Combination Changes Aizawa's Principle Of Operation And Eliminates A Feature Aizawa Repeatedly Identifies As Important**

Aizawa's approach monitors different individual detector signals and calculates pulse rate based on each individual photodetector signal. *See* Ex. 1006 ¶[0028] (referencing Figure 3 and explaining the pulse rate calculation for "the photodetector"); *see also id.* ¶¶ [0019] ("diagram of ***a*** pulse wave which is the output of ***a*** photodetector"), [0023], [0028] ("amplifying the outputs of the photodetectors," and "comput[ing] the number of outputs above the threshold value per unit time so as to calculate a pulse rate"); Ex. 2004 ¶102; Ex. 2026 76:13-22. Aizawa does not measure aggregated signals from detectors connected in parallel. *Id.* Instead, Aizawa repeatedly highlights that measuring pulse using a single detector's output helps address sensor dislocation. Ex. 1006 ¶¶[0027]-[0029], [0032], [0036]; *see also id.* ¶[0007] (discussing prior art where if the "position is dislocated, no output can be obtained"). Dr. Kenny confirmed Aizawa can detect a pulse rate based on the signal from just one photodetector. Ex. 2026 79:22-80:3. Aizawa also emphasizes that the detectors—regardless of number—"should be disposed around the light emitting diode 21 on a circle concentric to the light emitting diode 21 to detect a pulse wave." Ex. 1006 ¶[0032]; Ex. 2004 ¶102.

Petitioner ignores Aizawa's design and instead argues Mendelson 2003 would have motivated a POSITA to eliminate Aizawa's ability to monitor each detector

Filed June 28, 2022

On behalf of:
Patent Owner Masimo Corporation
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.

Petitioner,

v.

MASIMO CORPORATION,

Patent Owner.

IPR2020-01716
U.S. Patent 10,702,194

PATENT OWNER'S NOTICE OF APPEAL TO THE U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Pursuant to 28 U.S.C. § 1295(a)(4)(A), 35 U.S.C. §§ 141(c), 142, and 319, 37 C.F.R. §§ 90.2(a) and 90.3, and Rule 4(a) of the Federal Rules of Appellate Procedure, Patent Owner Masimo Corporation ("Masimo") hereby appeals to the United States Court of Appeals for the Federal Circuit from the Judgment – Final Written Decision (Paper 35) entered on April 28, 2022 (Attachment A) and from all underlying orders, decisions, rulings, and opinions that are adverse to Masimo related thereto and included therein, including those within the Decision Granting Institution of *Inter Partes* Review, entered May 5, 2021 (Paper 7). Masimo appeals the Patent Trial and Appeal Board's determination that claims 1-30 of U.S. Patent 10,702,194 are unpatentable, and all other findings and determinations, including but not limited to claim construction, as well as all other issues decided adverse to Masimo's position or as to which Masimo is dissatisfied in IPR2020-01716 involving Patent 10,702,194.

Masimo is concurrently providing true and correct copies of this Notice of Appeal, along with the required fees, to the Director of the United States Patent and Trademark Office and the Clerk of the United States Court of Appeals for the Federal Circuit.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: June 28, 2022

/Jarom Kesler/
Jarom D. Kesler (Reg. No. 57,046)

Attorney for Patent Owner
Masimo Corporation

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PTO/AIA/424 (04-14)

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)

First Named Inventor:	Jeroen Poeze	Nonprovisional Application Number (if known):	Herewith
Title of Invention:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently $0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.

2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed.

3. The applicable box is checked below:

I. ☑ Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)

i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.
---OR---
(b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.

ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, or the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.

II. ☐ Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)

i. A request for continued examination has been filed with, or prior to, this form.
ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature /Scott Cromar/	Date 2020-03-25
Name (Print/Typed) Scott Cromar	Practitioner Registration Number 65066

Note: *This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.**

☑ *Total of 1 forms are submitted.

a first amplifier configured to receive the first signal stream at an input of the first amplifier and at least amplify the first signal stream, and

a second amplifier configured to receive the second signal stream at an input of the second amplifier and at least amplify the second signal stream.

New claim 32 was added:

Claim 32. The physiological measurement system of Claim 2, wherein the handheld computing device comprises a mobile phone.

2. The following is an examiner's statement of reasons for allowance: The filed terminal disclaimer to co-pending application Nos. 16/829,510; 16/829,578; 16/834,467; 16/834,538; and 16/834,533 was approved on 05/06/2020 to resolve the provisional double patenting issues.

In regard to the related arts, Eastmond et al. (USPN 5,355,242 – applicant cited) teaches a device (Figs. 1 and 2A and associated descriptions) comprises: a first set of photodiodes (photodiodes in the first photodiode array 100, Figs. 1, 2A-1 and 2A-2), the first set of photodiodes comprising at least four photodiodes (Figs. 1 and 2A-2), the photodiodes of the first set of photodiodes connected to one another in parallel (parallel, Col 2 lines 19-35) to provide a first signal stream responsive to light from at least one of the one or more light emitters (data outputs to element 102, Fig. 1 and associated descriptions); and a second set of photodiodes (photodiodes in the second photodiode array 101, Figs. 1, 2A-1 and 2A-2), the second set of photodiodes comprising at least

four photodiodes (Figs. 1 and 2A-2), the photodiodes of the second set of photodiodes connected to one another in parallel (parallel, Col 2 lines 19-35) to provide a second signal stream responsive to light from at least one of the one or more light emitters (data outputs to element 103, Fig. 1 and associated descriptions) and a protrusion that extends over the photodiodes of the first and second sets of photodiodes (lens 200, Figs. 2A-1 and 2A-2 and associated descriptions; Col 3 lines 41-49). Chaiken et al. (USPN 6,223,063 – applicant cited) teaches an optical tissue modulation device (Figs. 1-3) comprises one or more emitter (Fig. 2) and four photodiodes disposed on a substrate (Fig. 1) and a cover with multiple protrusions placed on top of the photodiodes (Fig. 1). Kimura et al. (USPN 6,353,750 – applicant cited) teaches a noninvasive blood analyzer (Fig. 27) comprises one or more emitter (elements 11, Fig. 27), a photodiode array/ CCD (element 12, Fig. 27), and a cover with a protrusion (element 170, Fig. 27). Simonsen et al. (USPN 5,676,143 – applicant cited) teaches a glucose determination device (Figs. 15 and 21-22) comprises one or more emitters (emitters in Fig. 31), a first set of photodiodes, the first set of photodiodes comprising at least four photodiodes (row photodiodes 80a, Fig. 21), the photodiodes of the first set of photodiodes provides a first signal stream responsive to light from at least one of the one or more light emitters attenuated by body tissue (row photodiodes 80a, Fig. 21 and implement the measuring functions of Fig. 15 and 20); and a second set of photodiodes, the second set of photodiodes comprising at least four photodiodes (row photodiodes 80b, Fig. 21), the photodiodes of the second set of photodiodes a second signal stream responsive to light from at least one of the one or more light emitters attenuated by body tissue (row photodiodes 80b, Fig. 21 and implement the measuring functions of Fig. 15 and 20).

Wilcken et al. (USPN 7,230,227 – applicant cited) teaches a photodiode array (Figs. 1-5) comprises summing optical responses from multiple photodiodes, and the photodiodes of the first set of photodiodes connected to one another in parallel to provide a first signal stream responsive to light (Figs. 4-5). The teachings of Wilcken can be combined with the teachings of Simonsen in order to provide an alternative equivalent way to obtain the optical responses of the row photodiodes for glucose sensing.

However, the prior art of record does not teach or suggest “a first set of photodiodes, the first set of photodiodes comprising at least four photodiodes, the photodiodes of the first set of photodiodes connected to one another in parallel to provide a first signal stream, wherein each of the photodiodes of the first set of photodiodes has a corresponding window that allows light to pass through to the photodiode; a second set of photodiodes, the second set of photodiodes comprising at least four photodiodes, the photodiodes of the second set of photodiodes connected to one another in parallel to provide a second signal stream, wherein each of the photodiodes of the second set of photodiodes has a corresponding window that allows light to pass through to the photodiode; and a protruding convex surface, wherein the protruding convex surface is positioned such that the protruding convex surface is located between tissue of the user and the photodiodes of the first and second sets of photodiodes when the physiological sensor device is worn by the user”; or “a first set of photodiodes, the first set of photodiodes comprising at least four photodiodes, the photodiodes of the first set of photodiodes connected to one another in parallel to provide a first signal stream, wherein each of the photodiodes of the first set of

photodiodes has a corresponding window that allows light to pass through to the photodiode; a second set of photodiodes, the second set of photodiodes comprising at least four photodiodes, the photodiodes of the second set of photodiodes connected to one another in parallel to provide a second signal stream, wherein each of the photodiodes of the second set of photodiodes has a corresponding window that allows light to pass through to the photodiode; a wall that surrounds at least the first and second sets of photodiodes; and a cover comprising a protruding convex surface, wherein the protruding convex surface is above all of the photodiodes of the first and second sets of photodiodes, wherein at least a portion of the protruding convex surface is rigid, and wherein the cover is above the wall", in combination with the other claimed elements/ steps.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHU CHUAN LIU whose telephone number is (571)270-5507. The examiner can normally be reached on M-Th (8am-6pm).

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	Poeze et al.	
U.S. Patent No.:	10,702,194	Attorney Docket No.: 50095-0025IP1
Issue Date:	July 7, 2020	
Appl. Serial No.:	16/829,536	
Filing Date:	March 25, 2020	
Title:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS	

DECLARATION OF DR. THOMAS W. KENNY

Declaration

I declare that all statements made herein on my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable under Section 1001 of Title 18 of the United States Code.

By: ______________________________

Thomas W. Kenny, Ph.D.

VIII. GROUND 1 – Claims 1-18, 20, and 22-30 Are Rendered Obvious by Aizawa in view of Mendelson-2003, Ohsaki, and Mendelson-2006

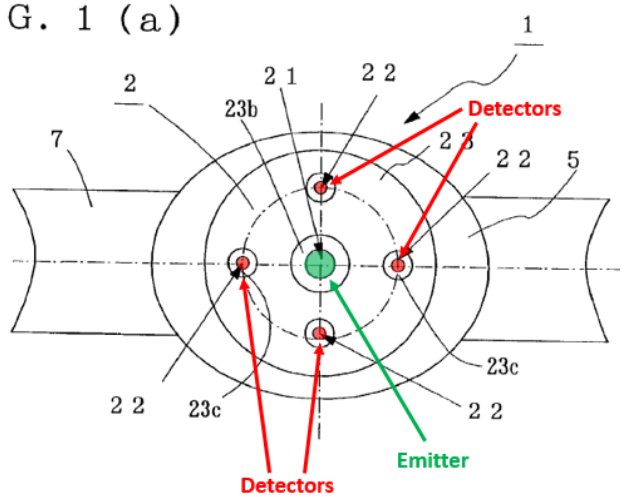
A. Combination of Aizawa, Mendelson-2003, Ohsaki, and Mendelson-2006

65. A POSITA would have been able and motivated to combine Aizawa, Mendelson-2003, Ohsaki, and Mendelson-2006 in the manner described below to derive various benefits.

Aizawa + Mendelson-2003

66. As I described above in Section VII.A, Aizawa teaches a first set of photodiodes in the form of four photodetectors 22 that are circularly arranged around a centrally located emitter, as shown below. APPLE-1006, [0023]. Moreover, a signal stream from this first set of photodiodes is sent to a drive detection circuit 24 that "amplif[ies] the outputs of the photodetectors." *Id.*

FIG. 1 (a)



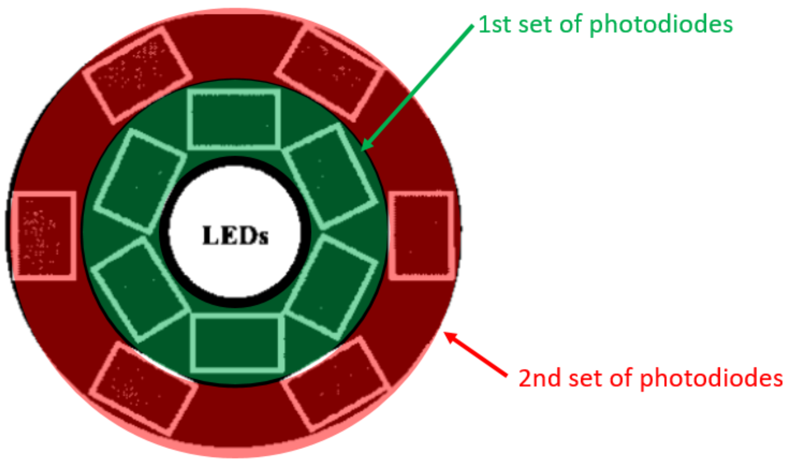
APPLE-1006, FIG. 1(a)

67. Aizawa teaches that 8 or more photodetectors may be provided to improve detection efficiency in some cases. *Id.*, [0032].

68. Aizawa does not expressly teach a second set of photodiodes that are connected to one another in parallel to provide a second signal stream as recited in claim 1 of the '194 patent. That is, while Aizawa teaches various ways of using a single ring of multiple detectors to improve detection efficiency, it does not explicitly mention that these multiple detectors may be provided as first and second sets of photodiodes that are each connected in parallel and provide first and second signal streams, respectively. APPLE-1006, [0013], [0030], [0032]. However, a POSITA would have realized that the arrangement of Aizawa's multiple detectors—which are arranged along a single ring—can be modified in view of Mendelson-2003 to be instead arranged along two rings to provide a wider detection area, thereby further advancing Aizawa's goal of improving detection efficiency through increased power savings as taught by Mendelson-2003. APPLE-1006, [0013], [0030], [0032]; APPLE-1024, 3017, 3019.

69. For example, as I show below, Mendelson-2003 teaches using two rings of photodiodes/detectors ("near positioned" detectors highlighted in green, and "far positioned" detectors highlighted in red) where the detectors in each of the near and far rings are "***wired in parallel*** and connected through a central hub to the common summing input of a current-to-voltage converter." APPLE-1024, 3017.

Mendelson-2003 further teaches that this configuration "widen[s] the active area of the PD which helps to collect a bigger portion of backscattered light intensity," thereby improving the light collection efficiency *Id.*, 3019. This configuration thus allows additional light to be captured, which in turn allows a lower brightness of LEDs to be used, which in turn would consume less power.



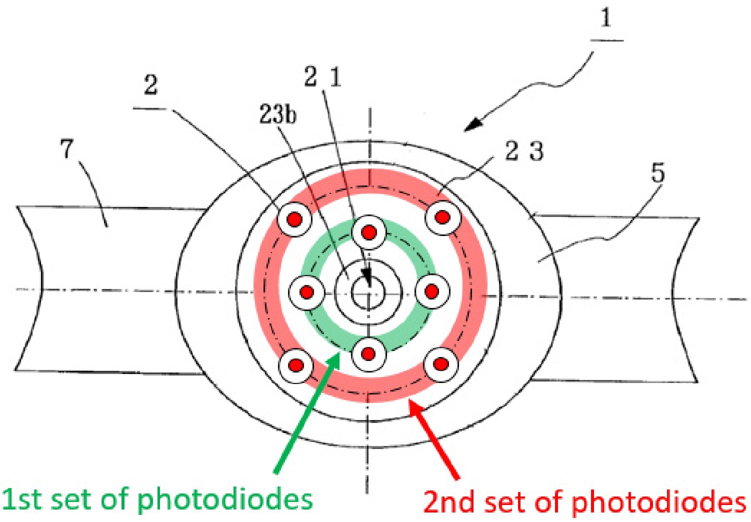
APPLE-1024, FIG. 1

70. Moreover, Mendelson-2003 is aimed at modifying conventional PD arrangements—***like that disclosed in Aizawa where a single ring of multiple PDs are mounted symmetrically around a light source***—to use two distinct rings of PDs that are mounted symmetrically around the light source. *See* APPLE-1024, 3016 (referring to conventional sensor designs based on "radial arrangement" of PDs or LEDs). Indeed, the prior art references mentioned in Mendelson-2003—*i.e.*, references [1]-[5]—describe conventional single ring devices such as those

found in Mendelson-1988 (which corresponds to reference) and Aizawa. *See* APPLE-1015, 168, FIG. 2(A); APPLE-1006, [0032]. Mendelson-2003's 2-ring configuration thus allows additional light to be captured, which enables use of lower brightness LEDs (*i.e.*, LEDs driven by a lower driving current) while still achieving acceptable signals from the PDs. APPLE-1024, 3017, 3019.

71. A POSITA in possession of both Aizawa and Mendelson-2003 would have recognized Mendelson-2003's use of two concentric rings (one that is near-positioned and another that is far-positioned) of photodiodes as a desirable detector configuration that would reap similar benefits for Aizawa in terms of achieving "power savings in the design of a more efficient" pulse sensing device. APPLE-1024, 3017. By using Mendelson-2003's power-saving (*i.e.*, efficiency-enhancing) PD configuration, the power consumption of a wrist-based pulse sensing device as in Aizawa can be reduced through use of a less bright and, hence, lower power-consuming LED. This would in turn allow Aizawa's wrist-based device to have a longer battery life. *Id.*

72. An example implementation of adding an additional ring of detectors to Aizawa, as per the teachings of Mendelson-2003, is shown below:



APPLE-1006, FIG. 1(a)

73. A POSITA would have further realized, in view of Mendelson-2003, that such a two-ring arrangement can be implemented in a wrist sensor device as in Aizawa by wiring each ring of detectors in parallel and summing the input of their respective streams. APPLE-1024, 3017; *see also* APPLE-1042, 5:20-67, FIGS 1-2; APPLE-1025, 4:23-30.

74. A POSITA also would have found it obvious to modify Aizawa with Mendelson-2003 to add an additional ring of detectors because doing so merely involves the use of known solutions to improve similar systems and methods in the same way. For instance, a POSITA would have recognized that applying Mendelson-2003's teachings regarding two, concentric rings of detectors that are each connected in parallel to Aizawa's sensor would have led to predictable results without significantly altering or hindering the functions performed by Aizawa's

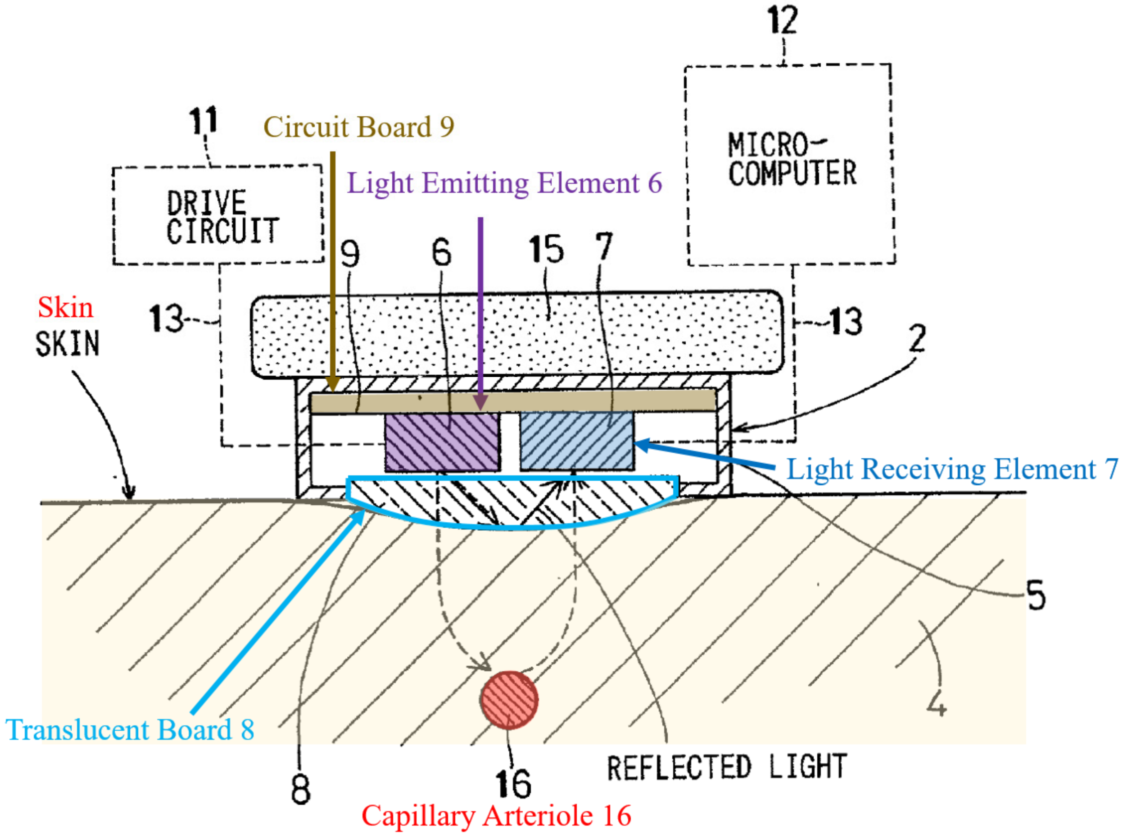
sensor. A POSITA would have been motivated to provide the well-known feature of providing multiple rings of photodiodes to a pulse sensor to achieve the predictable benefits offered by Mendelson-2003's description of the same. In fact, Aizawa itself contemplates, and is thus capable of supporting, the addition of extra detectors to improve light collection efficiency, although it does not disclose whether they may be arranged as two concentric rings. APPLE-1006, [0032]. Moreover, as noted above, Mendelson-2003 expressly contemplates adding an additional ring of detectors to a conventional 1-ring PD arrangement precisely as found in Aizawa. APPLE-1024, 3016.

Aizawa + Mendelson-2003 + Ohsaki

75. A POSITA would have been able and motivated to *further* combine the teachings of Aizawa-Mendelson-2003 with the teachings of Ohsaki such that the cover of Aizawa-Mendelson-2003's wrist-worn sensor would include a convex surface, improving adhesion between a subject's wrist and a surface of the sensor. APPLE-1014, [0025] (the convex surface prevents slippage of the detecting element from its position on the subject's wrist, and the convex nature of the surface suppresses the "variation of the amount of the reflected light" that reaches the detecting element).

76. In particular, Ohsaki describes a "detecting element" that includes "a package 5, a light emitting element 6 (e.g., LED), a light receiving element 7 (e.g., PD), and a translucent board 8." APPLE-1014, [0017]. "The package 5 has an opening and includes a" substrate in the form of "circuit board 9," on which light emitting element 6 and light receiving element 7 are arranged. *Id.*. As I show below in Ohsaki's FIG. 2, translucent board 8 is arranged such that, when the sensor is worn "on the user's wrist … the convex surface of the translucent board … is in intimate contact with the surface of the user's skin"; this contact between the convex surface and the user's skin is said to prevent slippage, which increases the strength of the signals obtainable by Ohsaki's sensor. APPLE-1014, [0015], [0017], [0025], FIGS. 1, 2, 4A, 4B.

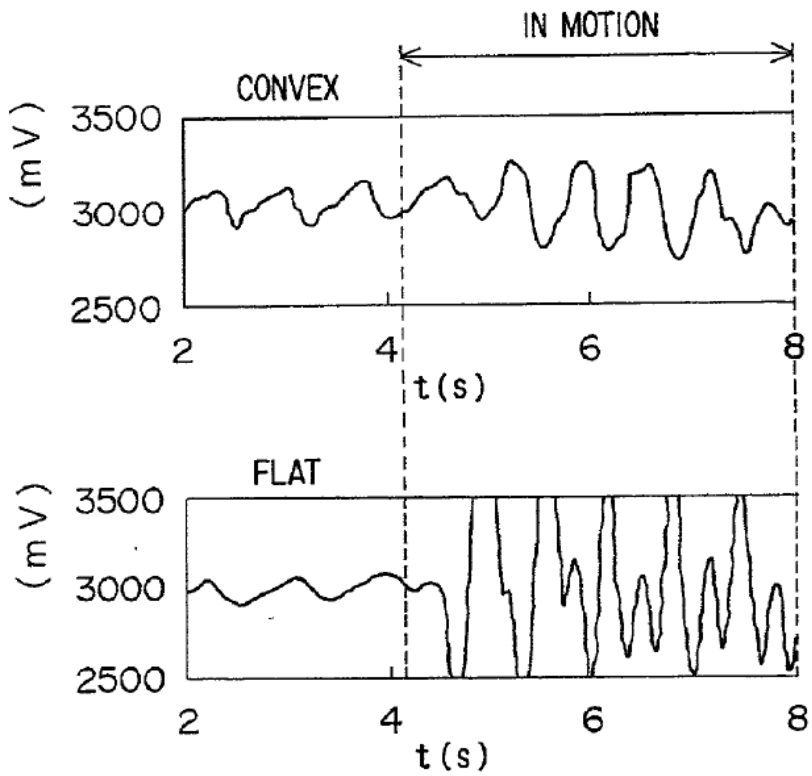
FIG. 2



APPLE-1014, FIG. 2 (annotated)

77. Here, Ohsaki explains that "if the translucent board 8 has a flat surface, the detected pulse wave is adversely affected by the movement of the user's wrist as shown in FIG. 4B (reproduced below)," but that if "the translucent board 8 has a convex surface…variation of the amount of the reflected light…that reaches the light receiving element 7 is suppressed." APPLE-1014, [0025]. The convex surface is also said to prevent "disturbance light from the outside" from penetrating translucent board 8. *Id*. Thus, when a convex cover is used, "the pulse wave can

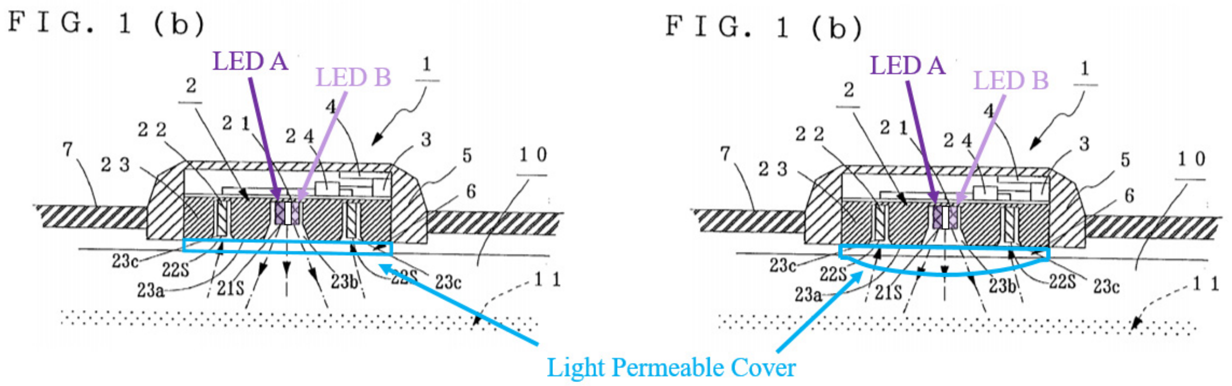
be detected without being affected by the movement of the user's wrist 4 as shown in FIG. 4A." *Id.*



APPLE-1014, FIGS. 4A, 4B

78. Thus, as I show below, a POSITA would have found it obvious to modify the sensor's flat cover (left) to include a lens/protrusion (right), similar to Ohsaki's translucent board 8, so as to improve adhesion between the user's wrist and the sensor's surface, improve detection efficiency, and protect the elements within the sensor housing. APPLE-1014, [0025] (explaining that the convex surface of translucent board 8 prevents slippage of a detecting element from its position on

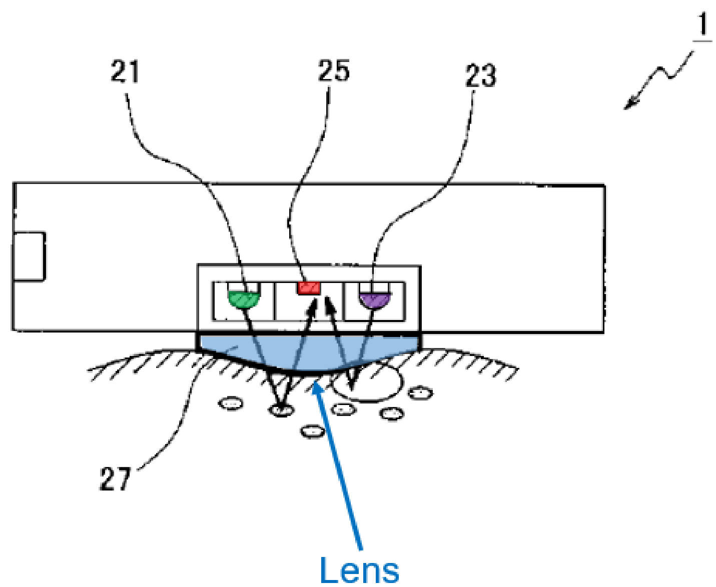
the wrist, and suppresses the "variation of the amount of the reflected light" that reaches the detecting element).



APPLE-1006, FIG. 1(b)

79. A POSITA would have combined the teachings of Aizawa-Mendelson-2003 and Ohsaki as doing so would have amounted to nothing more than the use of a known technique to improve similar devices in the same way. For instance, a POSITA would have recognized that incorporating Ohsaki's convex surface is simply improving Aizawa-Mendelson-2003's transparent plate 6 that has a flat surface to improve adhesion to a subject's skin and reduce variation in the signals detected by the sensor. Furthermore, the elements of the combined system would each perform similar functions they had been known to perform prior to the combination. That is, Aizawa-Mendelson-2003's transparent plate 6 would remain in the same position, performing the same function, but with a convex surface as taught by Ohsaki.

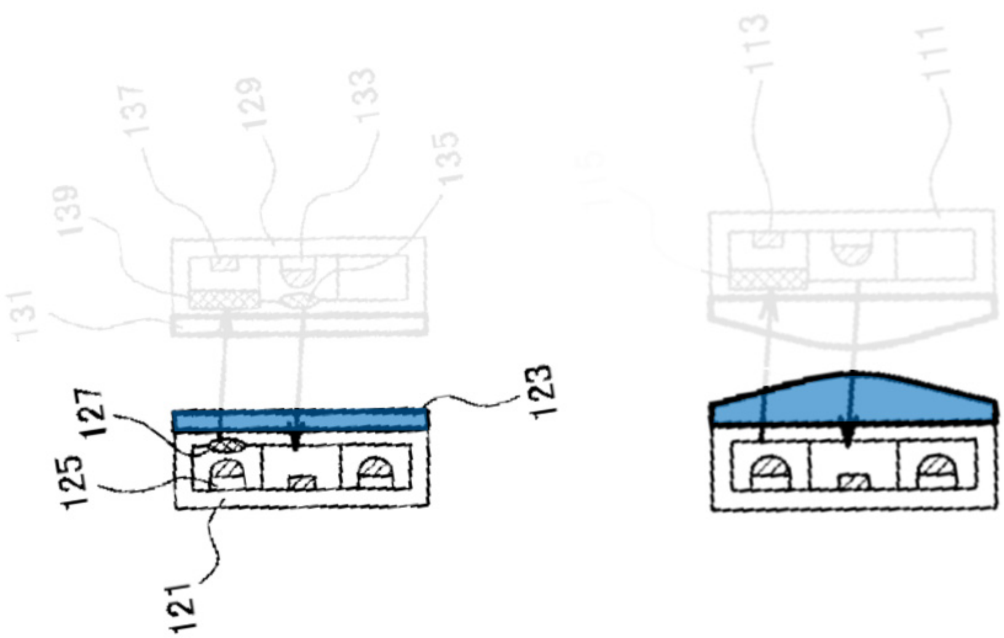
80. Incidentally, Inokawa provides further rationale for a POSITA to modify Aizawa to include a cover comprising a protruding convex surface, thus further strengthening the combination I just described above. For example, as shown below, Inokawa discloses a side lens 27:



APPLE-1008, FIG. 2

81. Inokawa further teaches that the "lens makes it possible to increase the light-gathering ability of the LED." APPLE-1008, [0015]. Thus, a POSITA would have understood that adding a protruded convex surface to Aizawa would have the additional benefit of increasing light collection efficiency, which would in turn lead to an improved signal-to-noise ratio and more reliable pulse detection. The lens of Inokawa provides precisely such an additional benefit to Aizawa's device by refracting/concentrating incoming light signals reflected by the blood. *Id.*

82. A POSITA would have further understood, in view of Inokawa, *how* to implement the convex surface of Ohsaki into Aizawa. For example, as shown below, Inokawa teaches that its cover may be either flat (left) such that "the surface is less prone to scratches," Inokawa at [0106], or in the form of a lens (right) to "increase the light-gathering ability of the LED." APPLE-1008, [0015].

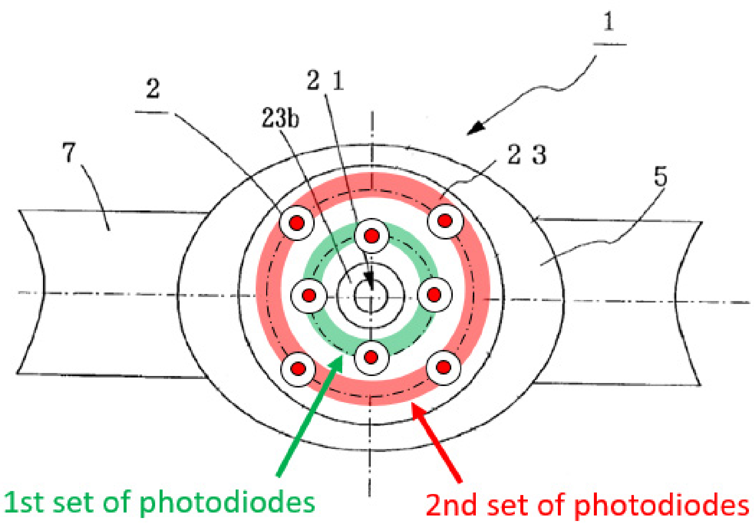


APPLE-1008, FIG. 17 (left), FIG. 16 (right)

83. A POSITA would have further recognized that the transparent acrylic material used to make Aizawa's plate can be readily formed to have a convex shape as in Inokawa. *See* APPLE-1009 at 3:46-51, FIG. 1.

Aizawa + Mendelson-2003 + Ohsaki + Mendelson-2006

efficiently detect the reflected light coming from the LED (and thus the LED will be able to operate at reduced power).



APPLE-1006, FIG. 1(a)

91. In the modified device shown above, where an additional ring of detectors has been added to Aizawa to form two concentric rings as discussed above in Section III.A.5, the inner ring of photodiodes (shown in green) can be equated to the claimed first set of photodiodes and includes at least four photodiodes. APPLE-1006, [0032], FIG. 1(a), FIG. 4(a).

[1e]: the photodiodes of the first set of photodiodes are connected to one another in parallel to provide a first signal stream, and

92. A POSITA would have recognized and/or found this feature for several reasons.

93. First, a POSITA would have recognized and/or found it obvious that an array of photodiodes, as found in the first set/ring of photodiodes in the modified Aizawa device, would be connected to one another in parallel to thereby form, essentially, a single continuous detector. APPLE-1025, 4:23-30. Indeed, a POSITA would have recognized that connecting multiple photodiodes together in parallel allows the current generated by the multiple photodiodes in the first set/ring to be added to one another, thereby resulting in a larger total current akin to what would be generated from a single, large detector, which is what the ring of detectors in Aizawa is in effect trying to mimic. This is an elementary concept in photosensor circuit design.

94. Second, Mendelson-2003, whose sensitivity-enhancing photodiode arrangement configuration is being used to modify Aizawa, expressly teaches that the photodiodes in each of the two sets (*i.e.*, rings) of photodiodes are connected to one another in parallel, thereby providing a distinct signal stream for each set/ring. In particular, Mendelson-2003 teaches that "[e]ach cluster of six PDs were wired in parallel and connected through a central hub to the common summing input of a current-to-voltage converter." APPLE-1024, 3017. Thus, as described above in Section VIII.A, a POSITA seeking to add a second ring of photodiodes to Aizawa would have looked to Mendelson-2003's teachings concerning how the two rings of photodiodes in the modified Aizawa device should be wired. Thus, a POSITA

would have found, in view of Mendelson-2003's express teachings, wiring two rings of photodiodes such that each ring/set of detectors "were wired in parallel" to be a routine and conventional design choice. Indeed, connecting photodiodes in a first set of photodiodes to one another in parallel to provide a first signal stream, as evidenced by Mendelson-2003, was common practice well before the Critical Date, and there was nothing new or inventive about changing the way such photodiodes are connected. *See* APPLE-1025, 4:23-30.

95. Moreover, a POSITA would have recognized that there can be multiple benefits to separately transmitting signals streams from the near and far detectors—as opposed to combining all the signals from the detectors into a single stream. For example, Mendelson '799 teaches that the detected values from each of its near and far detector arrays can be monitored such that "if both of them are not in the mentioned range, a corresponding alarm is generated indicative of that the sensor position should be adjusted." APPLE-1025, 13:19-30, FIG. 10A. In other words, monitoring each signal stream (from each ring of detectors) separately allows the system to determine when the sensor device is so severely located that its position should be adjusted. Mendelson '799 also teaches that its detector configuration can help detect "movement/breathing artifacts" and subsequently generate "a corresponding alarm signal." APPLE-1025, 13:31-42. Mendelson '799 is able to achieve this (along with other benefits) by maintaining separate

streams coming from each of its inner and outer rings of photodetectors. *Id.* Having two separate signal streams can also offer various advantages during research, testing, and/or calibration scenarios, where the ability to monitor each stream separately can be beneficial, for instance, to ensure that both rings are performing properly.

96. Additionally, a POSITA would have known that "[t]he intensity of the backscattered light decreases in direct proportion to the square of the distance between the photodetector and the LEDs." APPLE-1015, 168. In other words, a POSITA would have recognized that the photodiodes in the far ring (*i.e.,* second set of photodiodes) would receive reflected light having a lower intensity than that received by the photodiodes in the near ring (*i.e.*, first set of photodiodes) and would have been motivated and found it obvious to account for this discrepancy. Indeed, as shown in the plot below, "the light intensity detected by the photodiode decreases roughly exponentially as the radial distance from the LED's is increased." APPLE-1017, 801. This is because "the probability that the incident photons will be absorbed as they traverse a relatively longer path length before reaching the detector is increased." *Id.*

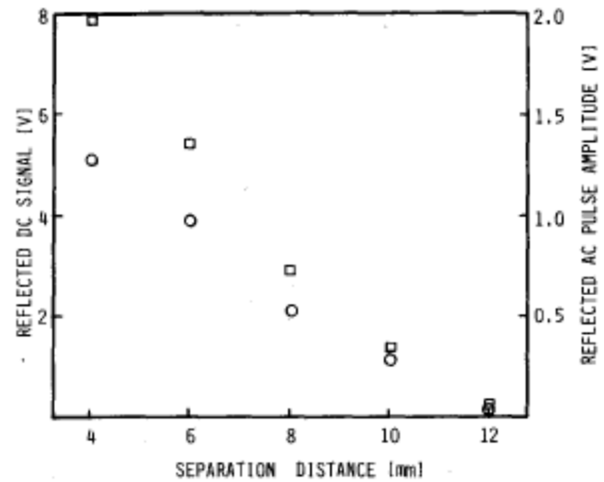


Fig. 4. The effect of LED/photodiode separation on the dc (□) and ac (○) components of the reflected infrared photoplethysmograms. Measurements were performed at a skin temperature of 43°C.

APPLE-1017, FIG. 4.

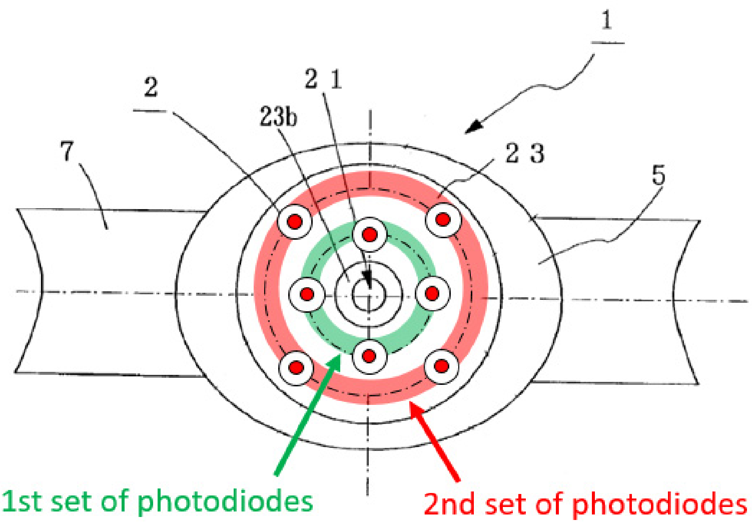
97. In Aizawa, a "drive detection circuit 24" is used for "amplifying the outputs of the photodetectors" and transmitting the amplified data to the arithmetic circuit 3, which computes the pulse rate. APPLE-1006, [0023], [0028]. In the modified Aizawa-Mendelson-2003 system, a POSITA would have recognized that the inner ring is likely to produce far greater currents compared to the outer ring due to the above-noted exponential relationship between detected light intensity and distance from the LED. APPLE-1017, 801. To ensure that the pulse rate data provided by the outer ring is preserved when combined with the pulse rate data provided by the inner ring, a POSITA would have found it obvious, in some implementations, to keep each ring separately wired and connected to its own amplifier (*i.e.*, drive detection circuit 24) to thereby keep the magnitude of the current signals provided by each ring approximately the same before being combined and transmitted to the

arithmetic circuit 3. Otherwise, if all the photodiodes in both the first and second rings in the modified Aizawa's sensor device are connected together in parallel such that a single stream is output (from both rings) to a single amplifier, signals detected by the near/first sets of detectors may drown out the weaker signals coming from the far/second sets of detectors, thereby diminishing the enhanced sensitivity and collection efficiency achieved through the widened detection area.

[1f]: each of the photodiodes of the first set of photodiodes has a corresponding window that allows light to pass through to the photodiode;

98. As I noted in Section VII.A, Aizawa teaches windows in the form of tapered cavities that provide an opening for each of the detectors (*e.g.*, each of the photodiodes of the first set of photodiodes) and that serve to increase, for instance, the concentration of light collected by the detectors, thereby increasing the signal to noise ratio. APPLE-1006, [0024], [0012].

multiple detectors in two concentric rings in order to, among other things, "widen[]the active area of the PD" and thereby "collect a bigger portion of backscattered light intensity." APPLE-1024, 3019. This effective widening of the detection are would result in "power savings achieved by widening the overall active area of the PD" as the detectors will be able to more efficiently detect the reflected light coming from the LED.



APPLE-1006, FIG. 1(a)

101. In the modified device shown above, where an additional ring of detectors has been added to Aizawa to form two concentric rings as discussed above in Section VIII.A, the outer ring of photodiodes (shown in red) can be equated to the claimed second set of photodiodes and includes at least four photodiodes. APPLE-1006, [0032], FIG. 1(a), FIG. 4(a).

[1i]: the photodiodes of the second set of photodiodes are connected to one another in parallel to provide a second signal stream, and

102. For reasons I discussed above for element [1e], the analysis for which is fully incorporated herein, a POSITA would have found it obvious that the photodiodes in the second/outer ring (*i.e.*, second set of photodiodes) in the Aizawa-Mendelson-2003-Ohsaki-Mendelson-2006 combination are connected to one another in parallel to provide a second signal stream.

[1j]: each of the photodiodes of the second set of photodiodes has a corresponding window that allows light to pass through to the photodiode;

103. For reasons I discussed above for element [1f], the analysis for which is fully incorporated herein, this element is satisfied by the Aizawa-Mendelson-2003-Ohsaki-Mendelson-2006 combination. In particular, each photodiode in modified Aizawa's second set of photodiodes would have included a corresponding window to allow light to pass through and to enhance light collection efficiency. APPLE-1006, [0024], [0012], FIG. 1(b).

[1k]: a wall that surrounds at least the first and second sets of photodiodes; and

104. In the Aizawa-Mendelson-2003-Ohsaki-Mendelson-2006 combination, Aizawa discloses a "a holder 23 for storing the above light emitting diode 21 and the photodetectors 22." APPLE-1006, [0023], [0024]. As shown below, the outer periphery of Aizawa's holder provides a circular wall (purple) that surrounds at least the first and second sets of photodiodes:

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Measurement Site and Photodetector Size Considerations in Optimizing Power Consumption of a Wearable Reflectance Pulse Oximeter

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Abstract– **Site selection and power consumption play a crucial role in optimizing the design of a wearable pulse oximeter for long-term telemedicine application. In this study we investigated the potential power saving in the design of a reflectance pulse oximeter taking into consideration measurement site and sensor configuration. *In-vivo* experiments suggest that battery longevity could be extended considerably by employing a wide annularly shaped photodetector ring configuration and performing SpO_2 measurements from the forehead region.**

Keywords– **pulse oximeter, wearable sensors, telemedicine**

I. INTRODUCTION

Noninvasive pulse oximetry is a widely accepted method for monitoring arterial hemoglobin oxygen saturation (SpO_2). Oxygen saturation is an important physiological variable since insufficient oxygen supply to vital organs can quickly lead to irreversible brain damage or result in death.

Pulse oximetry is based on spectrophotometric measurements of changes in blood color. The method relies on the detection of a photoplethysmographic (PPG) signal produced by variations in the quantity of arterial blood associated with periodic cardiac contraction and relaxation.

Pulse oximeter sensors are comprised of light emitting diodes (LEDs) and a silicon photodetector (PD). Typically, a red (R) LED with a peak emission wavelength around 660 nm, and an infrared (IR) LED with a peak emission wavelength around 940 nm are used as light sources. SpO_2 values are derived based on an empirically calibrated function by which the time-varying (AC) signal component of the PPG at each wavelength is divided by the corresponding time-invariant (DC) component which is due to light absorption and scattering by bloodless tissue, residual arterial blood volume during diastole, and non-pulsatile venous blood.

SpO_2 measurements can be performed in either transmission or reflection modes. In transmission mode, the sensor is usually attached across a fingertip or earlobe such that the LEDs and PD are placed on opposite sides of a pulsating vascular bed. Alternatively, in reflection pulse oximetry, the LEDs and PD are both mounted side-by-side facing the same side of the vascular bed. This configuration enables measurements from multiple locations on the body where transmission measurements are not feasible.

Backscattered light intensity can vary significantly between different anatomical locations. For example, optical reflectance from the forehead region is typically strong because of the relatively thin skin covering the skull combined with a higher density of blood vessels. On the contrary, other anatomical locations, such as the limbs or torso, have a much lower density of blood vessels and, in addition, lack a dominant skeletal structure in close proximity to the skin that helps to reflect some of the incident light. Therefore, the AC components of the reflected PPGs from these body locations are considerably smaller. Consequently, it is more difficult to perform accurate pulse oximetry measurement from these body locations without enhancing cutaneous circulation using artificial vasodilatation.

Sensors used with commercial transmission or reflection pulse oximeters employ a single PD element, typically with an active area of about 12-15mm^2. Normally, a relatively small PD chip is adequate for measuring strong transmission PPGs since most of the light emitted from the LEDs is diffused by the skin and subcutaneous tissues predominantly in a forward-scattering direction. However, in reflection mode, only a small fraction of the incident light is backscattered by the subcutaneous layers. Additionally, the backscattered light intensity reaching the skin surface is normally distributed over a relatively large area surrounding the LEDs. Hence, the design of a reflectance-mode pulse oximeter depends on the ability to fabricate a sensor that has improved sensitivity and can detect sufficiently strong PPGs from various locations on the body combined with sophisticated digital signal algorithms to process the relatively weak and often noisy signals.

To improve the accuracy and reliability of reflection pulse oximeters, several sensor designs have been described based on a radial arrangement of discrete PDs or LEDs. For example, Mendelson *et al* [1]-[2] and Konig *et al* [3] addressed the aspect of unfavorable SNR by developing a reflectance sensor prototype consisting of multiple discrete PDs mounted symmetrically around a pair of R and IR LEDs. Takatani *et al* [4]-[5] described a different sensor configuration based on 10 LEDs arranged symmetrically around a single PD chip.

The U.S. military has long been interested in combining noninvasive physiological sensors with wireless communication and global positioning to monitor soldier's vital signs in real-time. Similarly, remote monitoring of a person's health status who is located in a dangerous environment, such as mountain climbers or divers, could be beneficial. However, to gain better acceptability and address the unmet demand for long term continuous monitoring, several technical issues must be solved in order to design more compact sensors and instrumentation that are power

efficient, low-weight, reliable and comfortable to wear before they could be used routinely in remote monitoring applications. For instance, real-time continuous physiological monitoring from soldiers during combat using existing pulse oximeters is unsuitable because commercial oximeters involve unwieldy wires connected to the sensor, and sensor attachment to a fingertip restrains normal activity. Therefore, there is a need to develop a battery-efficient pulse oximeter that could monitor oxygen saturation and heart rate noninvasively from other locations on the body besides the fingertips.

To meet future needs, low power management without compromising signal quality becomes a key requirement in optimizing the design of a wearable pulse oximeter. However, high brightness LEDs commonly used in pulse oximeters requires relatively high current pulses, typically in the range between 100-200mA. Thus, minimizing the drive currents supplied to the LEDs would contribute considerably toward the overall power saving in the design of a more efficient pulse oximeter, particularly in wearable wireless applications. In previous studies we showed that the driving currents supplied to the LEDs in a reflection and transmission pulse oximeter sensors could be lowered significantly without compromising the quality of the PPGs by increasing the overall size of the PD [6]-[8]. Hence, by maximizing the light collected by the sensor, a very low power-consuming sensor could be developed, thereby extending the overall battery life of a pulse oximeter intended for telemedicine applications. In this paper we investigate the power savings achieved by widening the overall active area of the PD and comparing the LEDs driving currents required to produce acceptable PPG signals from the wrist and forehead regions as two examples of convenient body locations for monitoring SpO_2 utilizing a prototype reflectance pulse oximeter.

II. METHODOLOGY

A. Experimental setup

To study the potential power savings, we constructed a prototype reflectance sensor comprising twelve identical Silicon PD chips (active chip area: 2mm x 3mm) and a pair of R and IR LEDs. As shown schematically in Fig. 1, six PDs were positioned in a close inner-ring configuration at a radial distance of 6.0mm from the LEDs. The second set of six PDs spaced equally along an outer-ring, separated from the LEDs by a radius of 10.0mm. Each cluster of six PDs were wired in parallel and connected through a central hub to the common summing input of a current-to-voltage converter. The analog signals from the common current-to-voltage converter were subsequently separated into AC and DC components by signal conditioning circuitry. The analog signal components were then digitized at a 50Hz rate for 30 seconds intervals using a National Instruments DAQ card installed in a PC under the control of a virtual instrument implemented using LabVIEW 6.0 software.

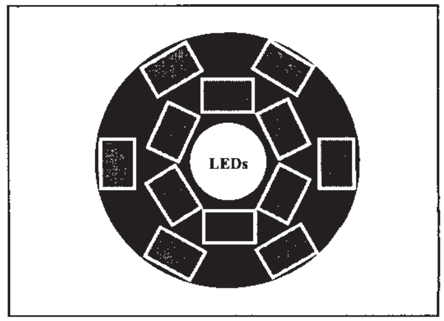

Fig. 1. Prototype reflectance sensor configuration showing the relative positions of the rectangular-shaped PDs and the LEDs.

B. In Vivo Experiments

A series of *in vivo* experiments were performed to quantify and compare the PPG magnitudes measured by the two sets of six PDs. The prototype sensor was mounted on the dorsal side of the wrist or the center of the forehead below the hairline. These representative regions were selected as two target locations for the development of a wearable telesensor because they provide a flat surface for mounting a reflectance sensor which for example could be incorporated into a wrist watch device or attached to a soldier's helmet without using a double-sided adhesive tape. After the sensor was securely attached, the minimum peak currents flowing through each LED was adjusted while the output of the amplifier was monitored continuously to assure that distinguishable and stable PPGs were observed from each set of PDs and the electronics were not saturated.

Two sets of measurements were acquired from each body location. In the first set of experiments we kept the currents supplied to the LEDs at a constant level and the magnitude of the PPGs measured from each set of six PDs were compared. To estimate the minimum peak currents required to drive the LEDs for the near and far-positioned PDs, we performed a second series of measurements where the driving currents were adjusted until the amplitude of the respective PPG reached approximately a constant amplitude.

III. RESULTS

Typical examples of reflected PPG signals measured by the inner set of six PDs from the forehead and wrist for a constant peak LED current (R: 8.5mA, IR: 4.2mA) are plotted respectively in Fig. 2.

The relative RMS amplitudes of the PPG signals measured by the six near (N) and far (F) PDs, and the combination of all 12 PDs (N+F) are plotted in Fig. 3(a) and 3(b) for a peak R LED drive current of 8.5mA and a peak IR LED drive current of 4.2mA, respectively. Analysis of the data revealed that there is a considerable difference between the signals measured by each set of PDs and amplitude of the respective PPG signals depends on measurement site.

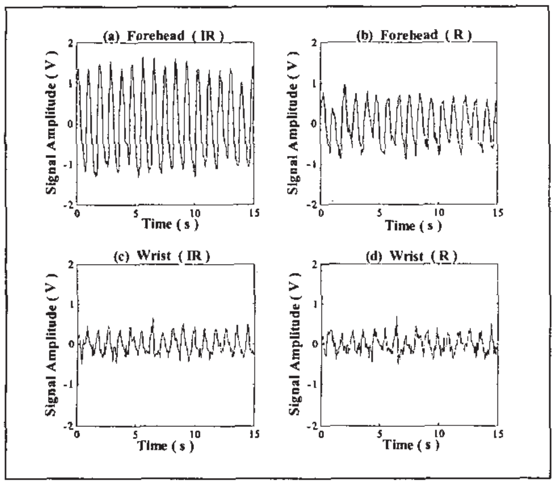

Fig. 2. Raw PPG signals measured from the forehead (*a* and *b*) and wrist (*c* and *d*) for constant LED driving currents.

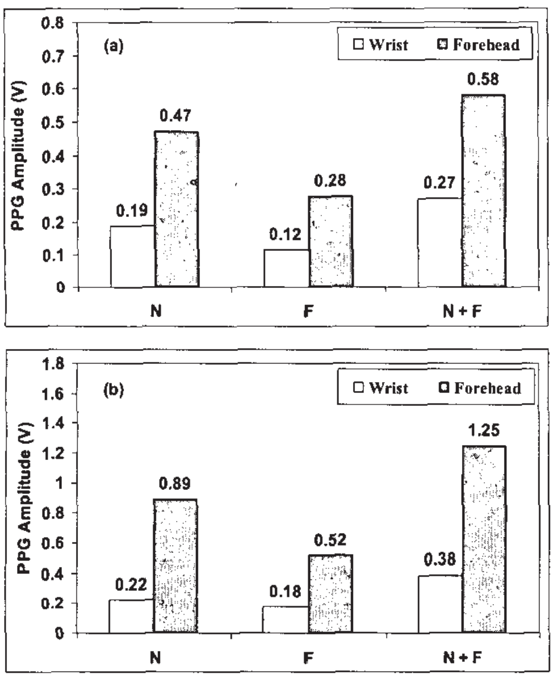

Fig. 3. PPG signal amplitudes measured by the near (N), far (F) and combination (N+F) PDs from the wrist and forehead for constant R and IR LED drive currents corresponding to 8.5mA (*a*) and 4.2mA (*b*), respectively.

Fig. 4 compares the relative peak LED currents required to maintain a constant AC RMS amplitude of approximately 0.840(±0.017)V for the N, F and (N+F) PDs measured from the forehead.

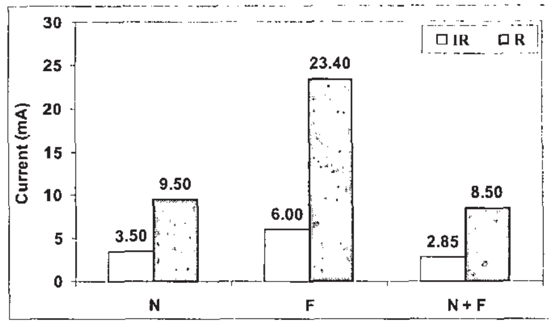

Fig. 4. Relative LED peak driving currents required to maintain a constant PPG amplitude of 0.840V RMS for the near (N), far (F) and combination (N+F) PD configurations. Measurements were obtained from the forehead.

IV. Discussion

The successful design of a practical wearable pulse oximeter presents several unique challenges. In addition to user acceptability, the other most important issues are sensor placement and power consumption. For example, utilizing disposable tape or a reusable spring-loaded device for attachment of pulse oximeter sensors, as commonly practiced in clinical medicine, poses significant limitations, especially in ambulatory applications.

Several studies have shown that oximetry readings may vary significantly according to sensor location. For example, tissue blood volume varies in different parts of the body depending on the number and arrangement of blood vessels near the surface of the skin. Other factors, such as sensor-to-skin contact, can influence the distribution of blood close to the skin surface and consequently can cause erroneous readings. Therefore, to ensure consistent performance, it is important to pay close attention to the design of optical sensors used in reflectance pulse oximetry and the selection of suitable sites for sensor attachment.

The current consumed by the LEDs in a battery powered pulse oximeter is inversely proportional to the battery life. Hence, minimizing the current required to drive the LEDs is a critical design consideration, particularly in optimizing the overall power consumption of a wearable pulse oximeter. However, reduced LED driving currents directly impacts the incident light intensity and, therefore, could lead to deterioration in the quality of the measured PPGs. Consequently, lower LED drive currents could result in unreliable and inaccurate reading by a pulse oximeter.

From the data presented in Fig. 2, it is evident that the amplitude and quality of the recorded PPGs vary significantly between the forehead and the wrist. We also observed that using relatively low peak LED driving currents, we had to apply a considerable amount of external pressure on the sensor in order to measure discernable PPG

signals from the wrist. In contrast, using minimal contact pressure and similar LED driving currents produced significantly larger and less noisy PPG signals from the forehead. These noticeable differences are due to the lower density of superficial blood vessels on the arms compared to the highly vascular forehead skin combined with a strong light reflection from the forehead bone. Additionally, during conditions of peripheral vasoconstriction, a sensor placed on the forehead can maintain stronger PPGs longer compared to a finger sensor [9].

Despite the noticeable differences between the PPG signals measured from the wrist and forehead, the data plotted in Fig. 3 also revealed that considerable stronger PPGs could be obtained by widening the active area of the PD which helps to collect a bigger proportion of backscattered light intensity. The additional increase, however, depends on the area and relative position of the PD with respect to the LEDs. For example, utilizing the outer-ring configuration, the overall increase in the average amplitudes of the R and IR PPGs measured from the forehead region was 23% and 40%, respectively. Similarly, the same increase in PD area produced an increase in the PPG signals measured from the wrist, but with a proportional higher increase of 42% and 73%.

The data presented in Fig. 4 confirmed that in order to produce constant PPG amplitudes, significantly higher currents are required to drive the LEDs when backscattered light is measured by the outer PD set compared to the inner set. This observation was expected since the backscattered light intensity measured is inversely related to the separation distance between the PD and the LEDs [10]. In comparing the three different PD configurations, we found that by combining both PD sets to simulate a single large PD area, it is possible to further reduce the driving currents of the LEDs without compromising the amplitude or quality of the detected PPGs.

Lastly, we used the LED peak driving currents plotted in Fig. 4 to estimate the expected battery life of a typical 220mAh Lithium coin size battery assuming that a similar battery is used to power the optical components of a wearable pulse oximeter. Table 1 summarizes the estimated battery life for the different PD configurations tested in this study. The calculations are based on LEDs pulsed continuously at a typical duty cycle of approximately 1.5%.

Table 1. Comparison of estimated battery life for different PD configurations. Values based on forehead measurements for a typical 220mAhr coin size battery.

PD CONFIGURATION	BATTERY LIFE [Days]
Near	45.8
Far	20.3
Near+Far	52.5

Note that the estimated values given in Table 1 are very conservative since they rely only on the power consumed by the LEDs without taking into consideration the additional power demand imposed by other components of a wearable pulse oximeter. Nevertheless, the considerable differences in the estimated power consumptions clearly points out the practical advantage gained by using a reflection sensor comprising a large ring-shaped PD area to perform SpO_2 measurements from the forehead region.

V. CONCLUSION

Site selection and LED driving currents are critical design consideration in optimizing the overall power consumption of a wearable battery-operated reflectance pulse oximeter. In this study we investigated the potential power saving in a ring-shaped sensor configuration comprising two sets of photodetectors arranged in a concentric ring configuration. *In-vivo* experiments revealed that battery longevity could be extended considerably by employing a wide annular PD and limiting SpO_2 measurements to the forehead region.

ACKNOWLEDGMENT

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US006801799B2

(12) **United States Patent**
Mendelson

(10) **Patent No.: US 6,801,799 B2**
(45) **Date of Patent: Oct. 5, 2004**

(54) **PULSE OXIMETER AND METHOD OF OPERATION**

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(73) Assignee: **Cybro Medical, Ltd.**, Haifa (IL)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **10/360,666**

(22) Filed: **Feb. 6, 2003**

(65) **Prior Publication Data**

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Related U.S. Application Data

(62) Division of application No. 09/939,391, filed on Aug. 24, 2001, now abandoned.

(30) **Foreign Application Priority Data**

Oct. 5, 2000 (IL) 138884

(51) **Int. Cl.**7 .... **A61B 5/00**
(52) **U.S. Cl.** **600/330**; 600/322; 600/336
(58) **Field of Search** 600/310, 322, 600/323, 330, 336

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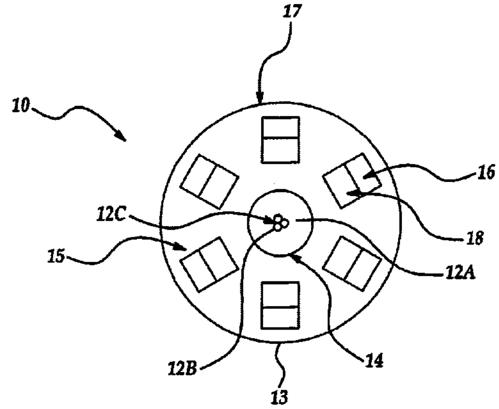
(74) *Attorney, Agent, or Firm*—Howard & Howard

(57) **ABSTRACT**

A sensor for use in an optical measurement device and a method for non-invasive measurement of a blood parameter. The sensor includes sensor housing, a source of radiation coupled to the housing, and a detector assembly coupled to the housing. The source of radiation is adapted to emit radiation at predetermined frequencies. The detector assembly is adapted to detect reflected radiation at least one predetermined frequency and to generate respective signals. The signals are used to determine the parameter of the blood.

5 Claims, 6 Drawing Sheets



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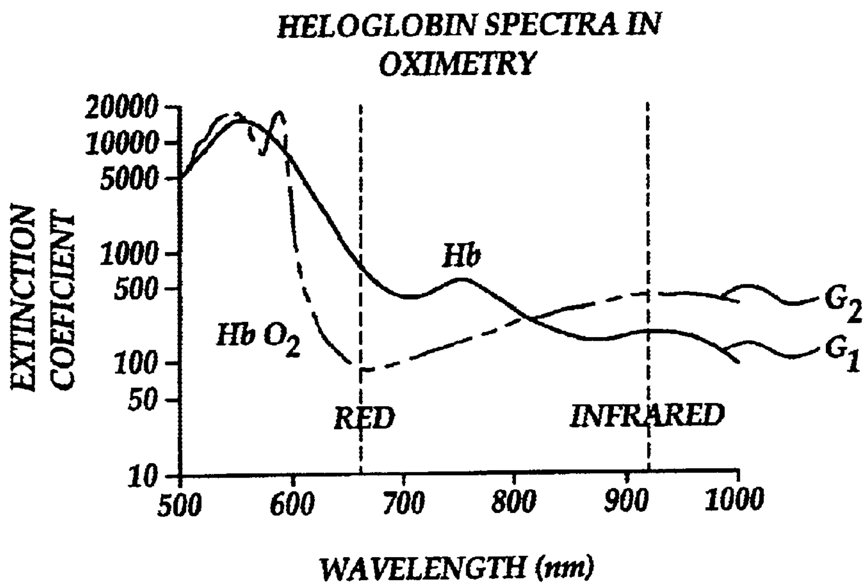


Figure 1

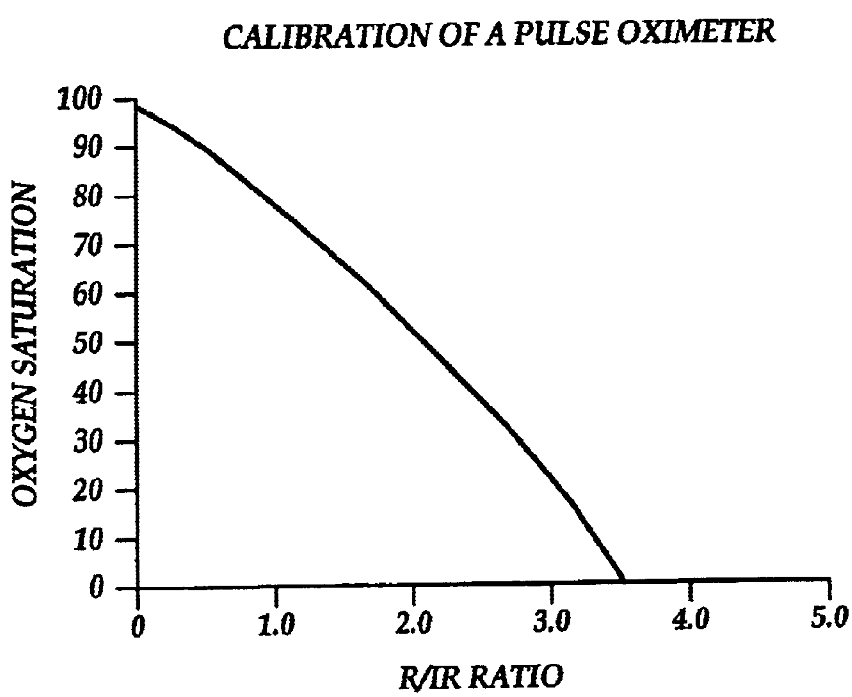


Figure 2

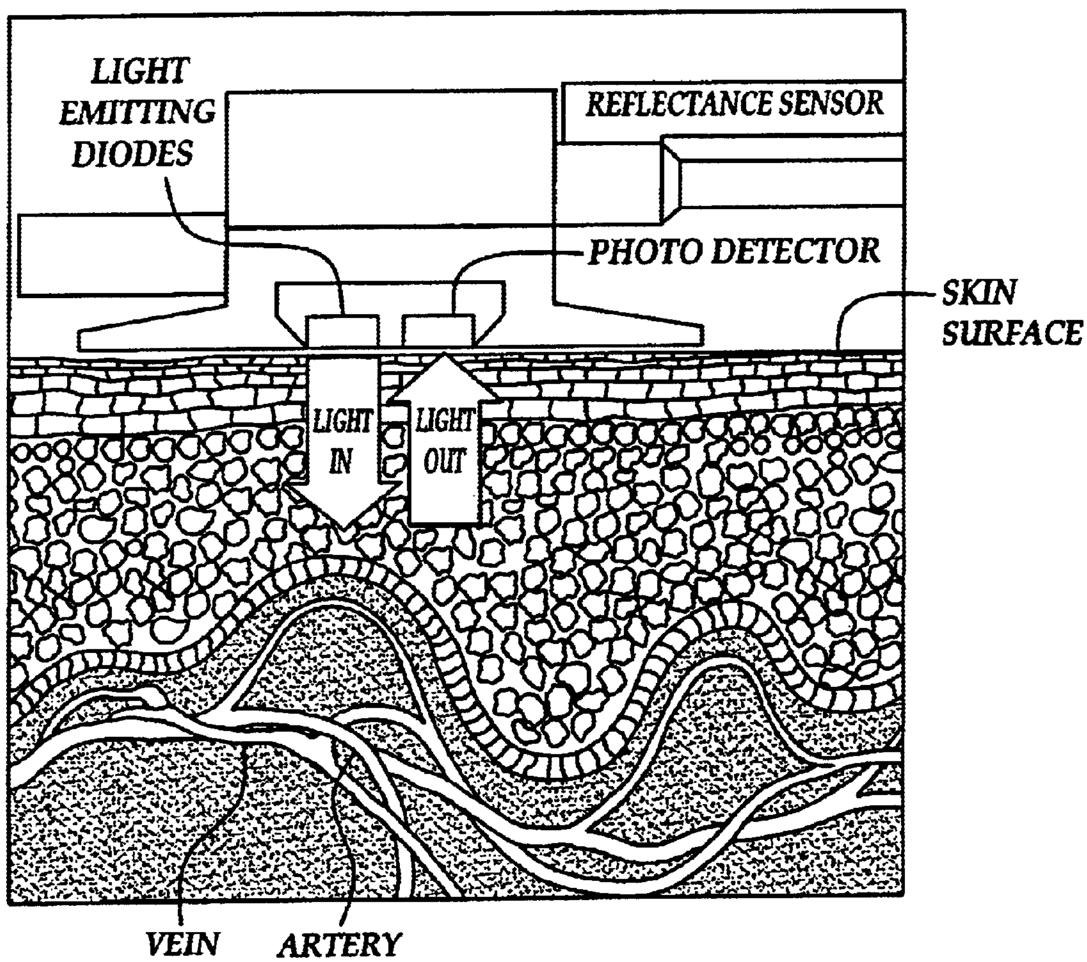


Figure 3

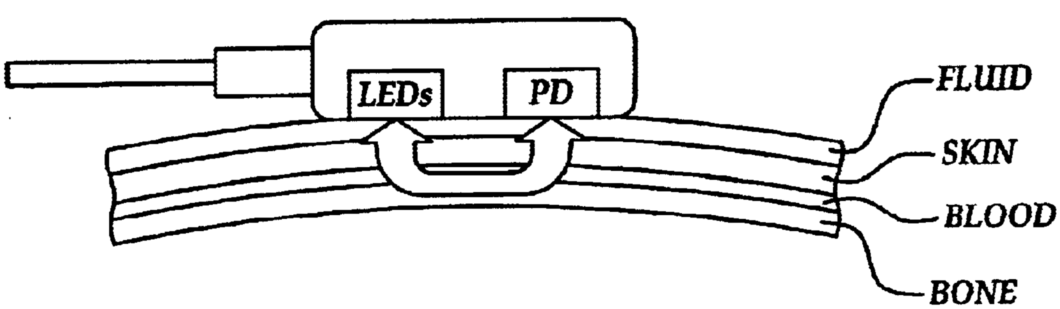


Figure 4

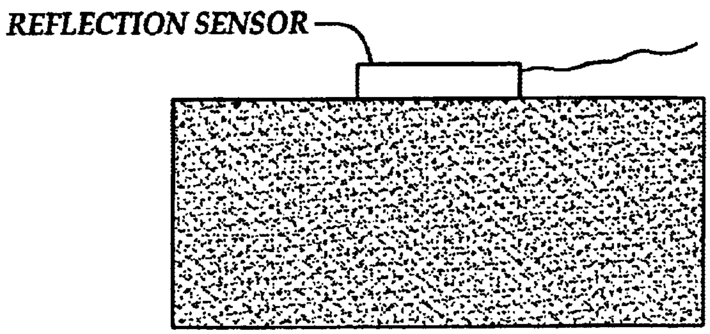


Figure 5A

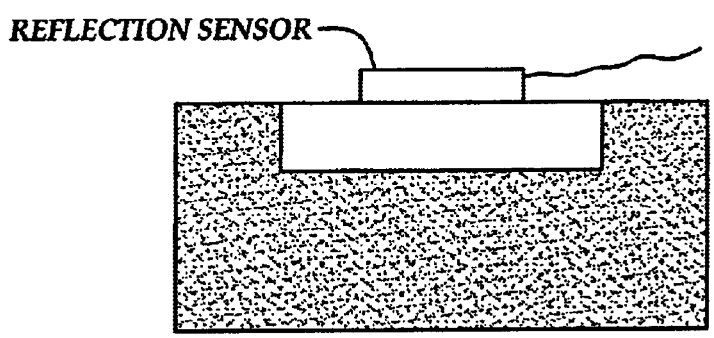


Figure 5B

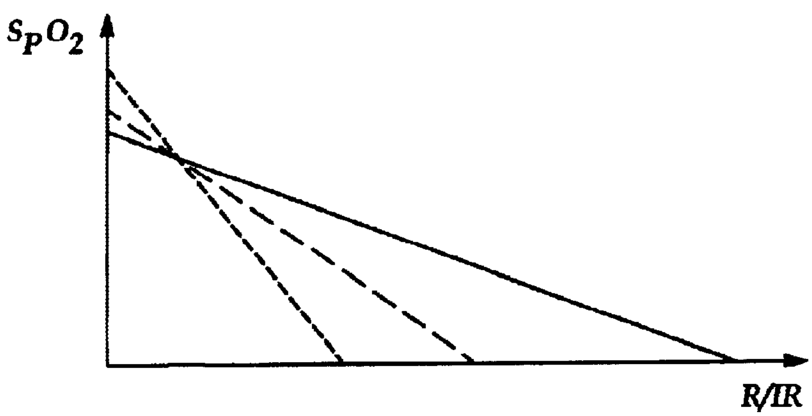


Figure 6

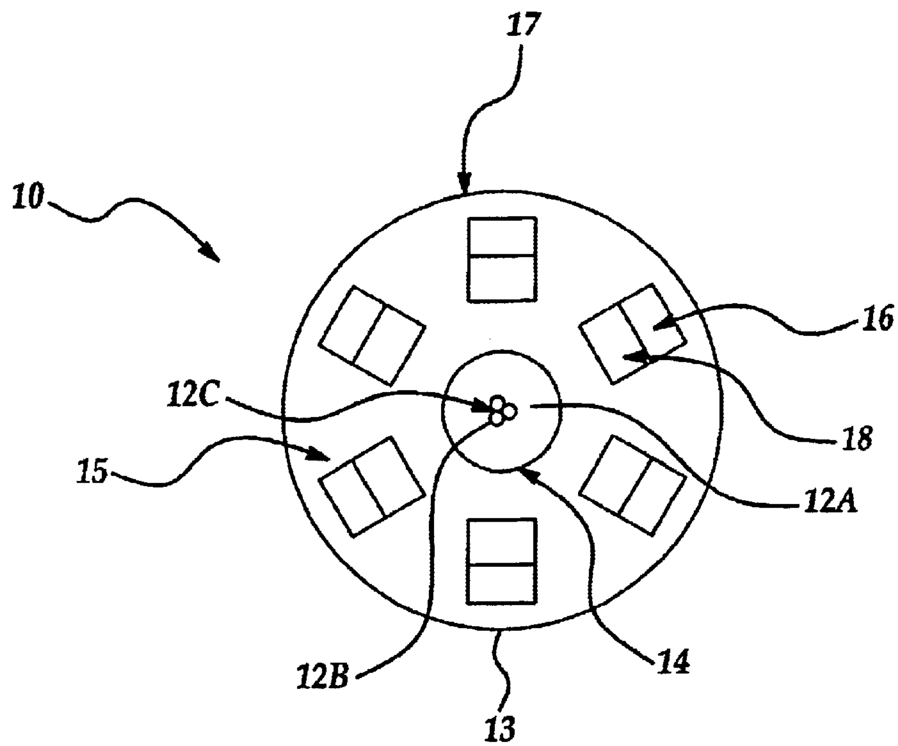


Figure 7

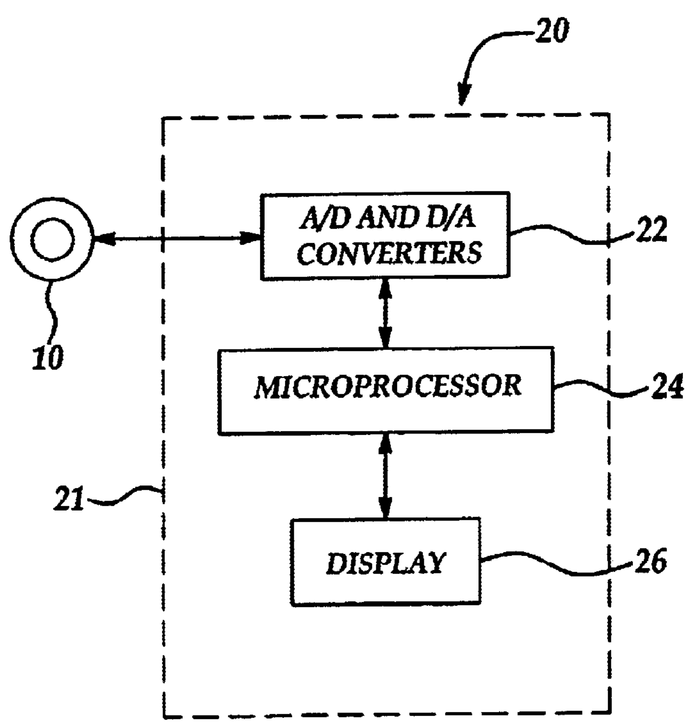


Figure 8

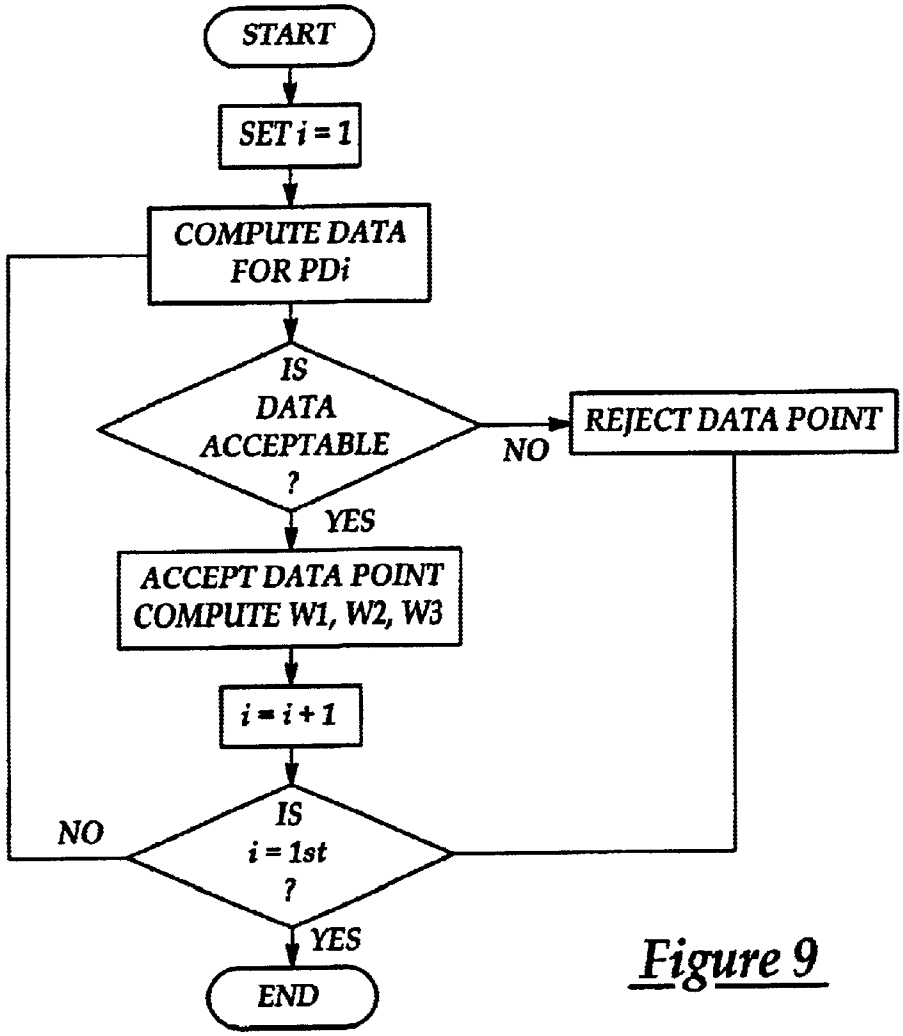


Figure 9

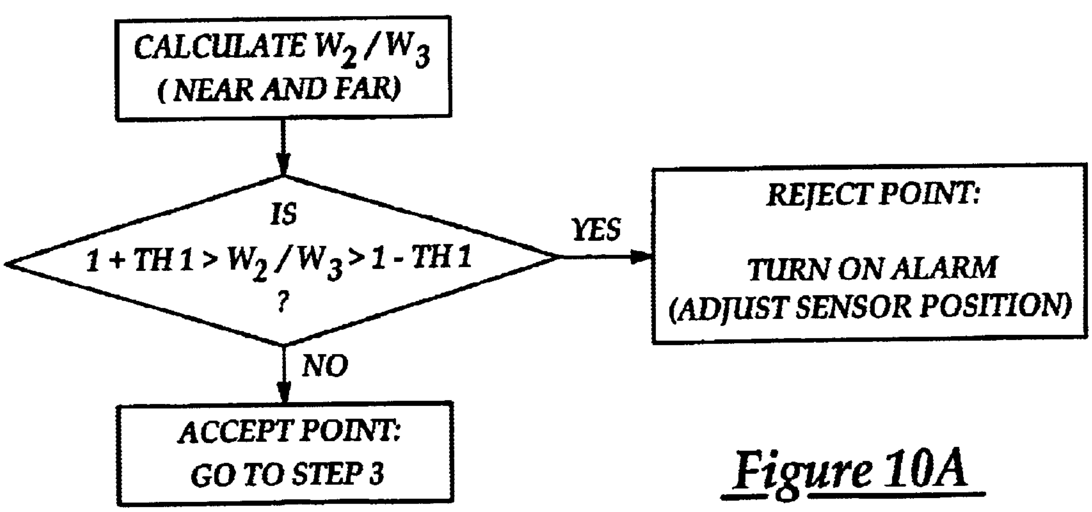


Figure 10A

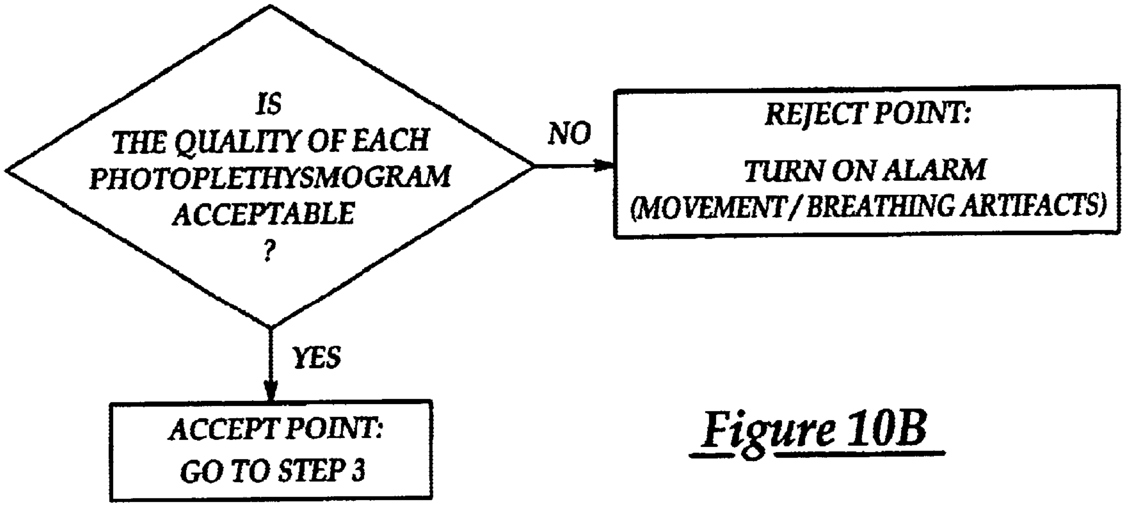


Figure 10B

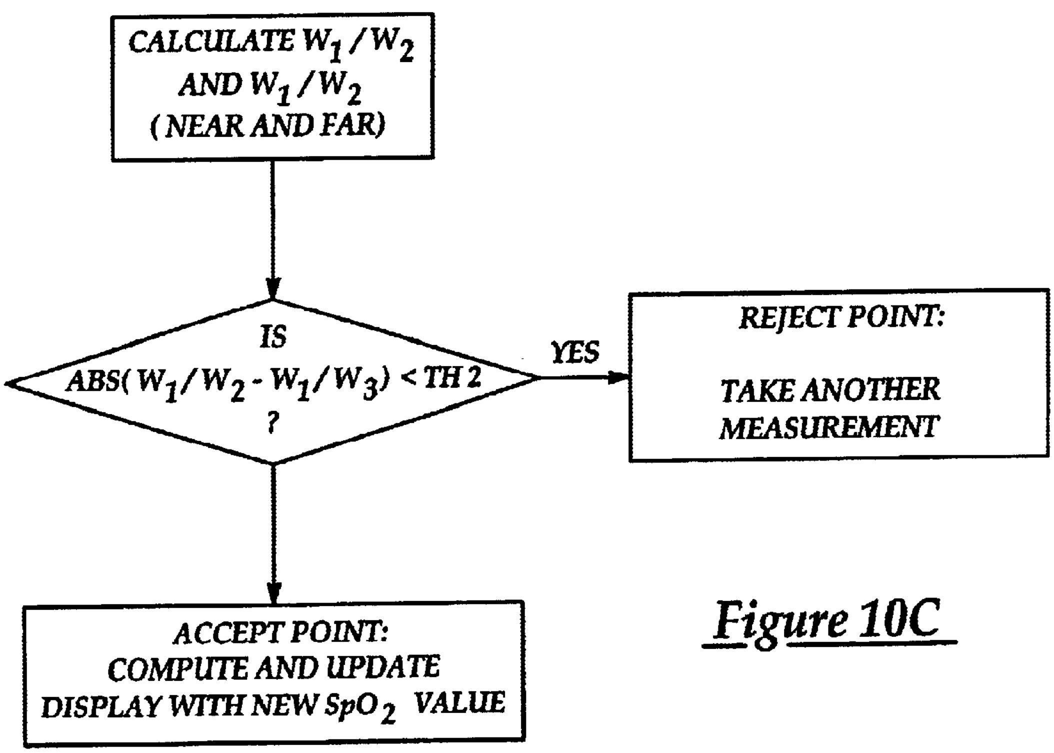


Figure 10C

PULSE OXIMETER AND METHOD OF OPERATION

This application is a divisional application of U.S. patent application Ser. No. 09/939,391 filed Aug. 24, 2001, now abandoned.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention is generally in the field of pulse oximetry, and relates to a sensor for use in a pulse oximeter, and a method for the pulse oximeter operation.

2. Background of the Invention

Oximetry is based on spectrophotometric measurements of changes in the color of blood, enabling the non-invasive determination of oxygen saturation in the patient's blood. Generally, oximetry is based on the fact that the optical property of blood in the visible (between 500 and 700 nm) and near-infrared (between 700 and 1000 nm) spectra depends strongly on the amount of oxygen in blood.

Referring to FIG. **1**, there is illustrated a hemoglobin spectra measured by oximetry based techniques. Graphs G**1** and G**2** correspond, respectively, to reduced hemoglobin, or deoxyhemoglobin (Hb), and oxygenated hemoglobin, or oxyhemoglobin (HbO_2), spectra. As shown, deoxyhemoglobin (Hb) has a higher optical extinction (i.e., absorbs more light) in the red region of spectrum around 660 nm, as compared to that of oxyhemoglobin (HbO_2). On the other hand, in the near-infrared region of the spectrum around 940 nm, the optical absorption by deoxyhemoglobin (Hb) is lower than the optical absorption of oxyhemoglobin (HbO_2).

Prior art non-invasive optical sensors for measuring arterial oxyhemoglobin saturation (SaO_2) by a pulse oximeter (termed SpO_2) are typically comprised of a pair of small and inexpensive light emitting diodes (LEDs), and a single highly sensitive silicon photodetector. A red (R) LED centered on a peak emission wavelength around 660 nm and an infrared (IR) LED centered on a peak emission wavelength around 940 nm are used as light sources.

Pulse oximetry relies on the detection of a photoplethysmographic signal caused by variations in the quantity of arterial blood associated with periodic contraction and relaxation of a patient's heart. The magnitude of this signal depends on the amount of blood ejected from the heart into the peripheral vascular bed with each systolic cycle, the optical absorption of the blood, absorption by skin and tissue components, and the specific wavelengths that are used to illuminate the tissue. SaO_2 is determined by computing the relative magnitudes of the R and IR photoplethysmograms. Electronic circuits inside the pulse oximeter separate the R and IR photoplethysmograms into their respective pulsatile (AC) and non-pulsatile (DC) signal components. An algorithm inside the pulse oximeter performs a mathematical normalization by which the time-varying AC signal at each wavelength is divided by the corresponding time-invariant DC component which results mainly from the light absorbed and scattered by the bloodless tissue, residual arterial blood when the heart is in diastole, venous blood and skin pigmentation.

Since it is assumed that the AC portion results only from the arterial blood component, this scaling process provides a normalized R/IR ratio (i.e., the ratio of AC/DC values corresponding to R- and IR-spectrum wavelengths, respectively), which is highly dependent on SaO_2, but is largely independent of the volume of arterial blood entering

the tissue during systole, skin pigmentation, skin thickness and vascular structure. Hence, the instrument does not need to be re-calibrated for measurements on different patients. Typical calibration of a pulse oximeter is illustrated in FIG. **2** by presenting the empirical relationship between SaO_2 and the normalized R/IR ratio, which is programmed by the pulse oximeters' manufacturers.

Pulse oximeters are of two kinds operating, respectively, in transmission and reflection modes. In transmission-mode pulse oximetry, an optical sensor for measuring SaO_2 is usually attached across a fingertip, foot or earlobe, such that the tissue is sandwiched between the light source and the photodetector.

In reflection-mode or backscatter type pulse oximetry, as shown in FIG. **3**, the LEDs and photodetector are both mounted side-by-side next to each other on the same planar substrate. This arrangement allows for measuring SaO_2 from multiple convenient locations on the body (e.g. the head, torso, or upper limbs), where conventional transmission-mode measurements are not feasible. For this reason, non-invasive reflectance pulse oximetry has recently become an important new clinical technique with potential benefits in fetal and neonatal monitoring. Using reflectance oximetry to monitor SaO_2 in the fetus during labor, where the only accessible location is the fetal scalp or cheeks, or on the chest in infants with low peripheral perfusion, provides several more convenient locations for sensor attachment.

Reflection pulse oximetry, while being based on similar spectrophotometric principles as the transmission one, is more challenging to perform and has unique problems that can not always be solved by solutions suitable for solving the problems associated with the transmission-mode pulse oximetry. Generally, comparing transmission and reflection pulse oximetry, the problems associated with reflection pulse oximetry consist of the following:

In reflection pulse oximetry, the pulsatile AC signals are generally very small and, depending on sensor configuration and placement, have larger DC components as compared to those of transmission pulse oximetry. As illustrated in FIG. **4**, in addition to the optical absorption and reflection due to blood, the DC signal of the R and IR photoplethysmograms in reflection pulse oximetry can be adversely affected by strong reflections from a bone. This problem becomes more apparent when applying measurements at such body locations as the forehead and the scalp, or when the sensor is mounted on the chest over the ribcage. Similarly, variations in contact pressure between the sensor and the skin can cause larger errors in reflection pulse oximetry (as compared to transmission pulse oximetry) since some of the blood near the superficial layers of the skin may be normally displaced away from the sensor housing towards deeper subcutaneous structures. Consequently, the highly reflective bloodless tissue compartment near the surface of the skin can cause large errors even at body locations where the bone is located too far away to influence the incident light generated by the sensor.

Another problem with currently available reflectance sensors is the potential for specular reflection caused by the superficial layers of the skin, when an air gap exists between the sensor and the skin, or by direct shunting of light between the LEDs and the photodetector through a thin layer of fluid which may be due to excessive sweating or from amniotic fluid present during delivery.

It is important to keep in mind the two fundamental assumptions underlying the conventional dual-wavelength pulse oximetry, which are as follows:

(1) the path of light rays with different illuminating wavelengths in tissue are substantially equal and, therefore, cancel each other; and (2) each light source illuminates the same pulsatile change in arterial blood volume.

Furthermore, the correlation between optical measurements and tissue absorptions in pulse oximetry are based on the fundamental assumption that light propagation is determined primarily by absorbable due to Lambent-Beer's law neglecting multiple scattering effects in biological tissues. In practice, however, the optical paths of different wavelengths in biological tissues is known to vary more in reflectance oximetry compared to transmission oximetry, since it strongly depends on the light scattering properties of the illuminated tissue and sensor mounting.

Several human validation studies, backed by animal investigations, have suggested that uncontrollable physiological and physical parameters can cause large variations in the calibration curve of reflectance pulse oximeters primarily at low oxygen saturation values below 70%. It was observed that the accuracy of pulse oximeters in clinical use might be adversely affected by a number of physiological parameters when measurements are made from sensors attached to the forehead, chest, or the buttock area. While the exact sources of these variations are not fully understood, it is generally believed that there are a few physiological and anatomical factors that may be the major source of these errors. It is also well known for example that changes in the ratio of blood to bloodless tissue volumes may occur through venous congestion, vasoconstriction/vasodilatation, or through mechanical pressure exerted by the sensor on the skin.

Additionally, the empirically derived calibration curve of a pulse oximeter can be altered by the effects of contact pressure exerted by the probe on the skin. This is associated with the following. The light paths in reflectance oximetry are not well defined (as compared to transmission oximetry), and thus may differ between the red and infrared wavelengths. Furthermore, the forehead and scalp areas consist of a relatively thin subcutaneous layer with the cranium bone underneath, while the tissue of other anatomical structures, such as the buttock and limbs, consists of a much thicker layer of skin and subcutaneous tissues without a nearby bony support that acts as a strong light reflector.

Several in vivo and in vitro studies have confirmed that uncontrollable physiological and physical parameters (e.g., different amounts of contact pressure applied by the sensor on the skin, variation in the ratio of bloodless tissue-to-blood content, or site-to-site variations) can often cause large errors in the oxygen saturation readings of a pulse oximeter, which are normally derived based on a single internally-programmed calibration curve. The relevant in vivo studies are disclosed in the following publications:

1. Dassel, et al., "Effect of location of the sensor on reflectance pulse oximetry", British Journal of Obstetrics and Gynecology, vol. 104, pp. 910–916, (1997);

2. Dassel, et al., "Reflectance pulse oximetry at the forehead of newborns: The influence of varying pressure on the probe", Journal of Clinical Monitoring, vol. 12, pp. 421–428, (1996).

The relevant in vitro studies are disclosed, for example in the following publication:

3. Edrich et al., "Fetal pulse oximetry: influence of tissue blood content and hemoglobin concentration in a new in-vitro model", European Journal of Obstetrics and Gynecology and Reproductive Biology, vol. 72, suppl. 1, pp. S29–S34, (1997).

Improved sensors for application in dual-wavelength reflectance pulse oximetry have been developed. As disclosed in the following publication: Mendelson, et al., "Noninvasive pulse oximetry utilizing skin reflectance photoplethysmography", IEEE Transactions on Biomedical Engineering, vol. 35, no. 10, pp. 798–805 (1988), the total amount of backscattered light that can be detected by a reflectance sensor is directly proportional to the number of photodetectors placed around the LEDs. Additional improvements in signal-to-noise ratio were achieved by increasing the active area of the photodetector and optimizing the separation distance between the light sources and photodetectors.

Another approach is based on the use of a sensor having six photodiodes arranged symmetrically around the LEDs that is disclosed in the following publications:

4. Mendelson, et al., "Design and evaluation of a new reflectance pulse oximeter sensor", Medical Instrumentation, vol. 22, no. 4, pp. 167–173 (1988); and

5. Mendelson, et al., "Skin reflectance pulse oximetry: in vivo measurements from the forearm and calf", Journal of Clinical Monitoring, vol. 7, pp. 7–12, (1991).

According to this approach, in order to maximize the fraction of backscattered light collected by the sensor, the currents from all six photodiodes are summed electronically by internal circuitry in the pulse oximeter. This configuration essentially creates a large area photodetector made of six discrete photodiodes connected in parallel to produce a single current that is proportional to the amount of light backscattered from the skin. Several studies showed that this sensor configuration could be used successfully to accurately measure SaO_2 from the forehead, forearm and the calf on humans. However, this sensor requires a means for heating the skin in order to increase local blood flow, which has practical limitations since it could cause skin burns.

Yet another prototype reflectance sensor is based on eight dual-wavelength LEDs and a single photodiode, and is disclosed in the following publication: Takatani et al., "Experimental and clinical evaluation of a noninvasive reflectance pulse oximeter sensor", Journal of Clinical Monitoring, vol. 8, pp. 257–266 (1992). Here, four R and four IR LEDs are spaced at 90-degree intervals around the substrate and at an equal radial distance from the photodiode.

A similar sensor configuration based on six photodetectors mounted in the center of the sensor around the LEDs is disclosed in the following publication: Konig, et al., "Reflectance pulse oximetry—principles and obstetric application in the Zurich system", Journal of Clinical Monitoring, vol. 14, pp. 403–412 (1998).

According to the techniques disclosed in all of the above publications, only LEDs of two wavelengths, R and IR, are used as light sources, and the computation of SaO_2 is based on reflection photoplethysmograms measured by a single photodetector, regardless of whether one or multiple photodiodes chips are used to construct the sensor. This is because of the fact that the individual signals from the photodetector elements are all summed together electronically inside the pulse oximeter. Furthermore, while a radially-symmetric photodetector array can help to maximize the detection of backscattered light from the skin and minimize differences from local tissue inhomogeneity, human and animal studies confirmed that this configuration can not completely eliminate errors caused by pressure differences and site-to-site variations.

The use of a nominal dual-wavelength pair of 735/890 nm was suggested as providing the best choice for optimizing

accuracy, as well as sensitivity in dual-wavelength reflectance pulse oximetry, in U.S. Pat. Nos. 5,782,237 and 5,421,329. This approach minimizes the effects of tissue heterogeneity and enables to obtain a balance in path length changes arising from perturbations in tissue absorbance. This is disclosed in the following publications:

6. Mannheimer at al., "Physio-optical considerations in the design of fetal pulse oximetry sensors", European Journal of Obstetrics and Gynecology and Reproductive Biology, vol. 72, suppl. 1, pp. S9–S19, (1997); and

7. Mannheimer at al., "Wavelength selection for low-saturation pulse oximetry", IEEE Transactions on Biomedical Engineering, vol. 44, no. 3, pp. 48–158 (1997)].

However, replacing the conventional R wavelength at 660 nm, which coincides with the region of the spectrum where the difference between the extinction coefficient of Hb and HbO_2 is maximal, with a wavelength emitting at 735 nm, not only lowers considerably the overall sensitivity of a pulse oximeter, but does not completely eliminate errors due to sensor placement and varying contact pressures.

Pulse oximeter probes of a type comprising three or more LEDs for filtering noise and monitoring other functions, such as carboxyhemoglobin or various indicator dyes injected into the blood stream, have been developed and are disclosed, for example, in WO 00/32099 and U.S. Pat. No. 5,842,981. The techniques disclosed in these publications are aimed at providing an improved method for direct digital signal formation from input signals produced by the sensor and for filtering noise.

None of the above prior art techniques provides a solution to overcome the most essential limitation in reflectance pulse oximetry, which requires the automatic correction of the internal calibration curve from which accurate and reproducible oxygen saturation values are derived, despite variations in contact pressure or site-to-site tissue heterogeneity.

In practice, most sensors used in reflection pulse oximetry rely on closely spaced LED wavelengths in order to minimize the differences in the optical path lengths of the different wavelengths. Nevertheless, within the wavelength range required for oximetry, even closely spaced LEDs with closely spaced wavelengths mounted on the same substrate can lead to large random error in the final determination of SaO_2.

SUMMARY OF THE INVENTION AND ADVANTAGES

The object of the invention is to provide a novel sensor design and method that functions to correct the calibration relationship of a reflectance pulse oximeter, and reduce measurement inaccuracies in general. Another object of the invention is to provide a novel sensor and method that functions to correct the calibration relationship of a reflectance pulse oximeter, and reduce measurement inaccuracies in the lower range of oxygen saturation values (typically below 70%), which is the predominant range in neonatal and fetal applications.

Yet another object of the present invention is to provide automatic correction of the internal calibration curve from which oxygen saturation is derived inside the oximeter in situations where variations in contact pressure or site-to-site tissue heterogeneity may cause large measurement inaccuracies.

Another object of the invention is to eliminate or reduce the effect of variations in the calibration of a reflectance pulse oximeter between subjects, since perturbations caused by contact pressure remain one of the major sources of errors in reflectance pulse oximetry. In fetal pulse oximetry, there are additional factors, which must be properly compensated for in order to produce an accurate and reliable measurement of oxygen saturation. For example, the fetal head is usually the presenting part, and is a rather easily accessible location for application of reflectance pulse oximetry. However, uterine contractions can cause large and unpredictable variations in the pressure exerted on the head and by the sensor on the skin, which can lead to large errors in the measurement of oxygen saturation by a dual-wavelength reflectance pulse oximeter. Another object of the invention is to provide accurate measurement of oxygen saturation in the fetus during delivery.

The basis for the errors in the oxygen saturation readings of a dual-wavelength pulse oximeter is the fact that, in practical situations, the reflectance sensor applications affect the distribution of blood in the superficial layers of the skin. This is different from an ideal situation, when a reflectance sensor measures light backscattered from a homogenous mixture of blood and bloodless tissue components. Therefore, the R and IR DC signals practically measured by photodetectors contain a relatively larger proportion of light absorbed by and reflected from the bloodless tissue compartments. In these uncontrollable practical situations, the changes caused are normally not compensated for automatically by calculating the normalized R/IR ratio since the AC portions of each photoplethysmogram, and the corresponding DC components, are affected differently by pressure or site-to-site variations. Furthermore, these changes depend not only on wavelength, but depend also on the sensor geometry, and thus cannot be eliminated completely by computing the normalized R/IR ratio, as is typically the case in dual-wavelength pulse oximeters.

The inventor has found that the net result of this nonlinear effect is to cause large variations in the slope of the calibration curves. Consequently, if these variations are not compensated automatically, they will cause large errors in the final computation of SpO_2, particularly at low oxygen saturation levels normally found in fetal applications.

Another object of the present invention is to compensate for these variations and to provide accurate measurement of oxygen saturation. The invention consists of, in addition to two measurement sessions typically carried out in pulse oximetry based on measurements with two wavelengths centered around the peak emission values of 660 nm (red spectrum) and 940 nm±20 nm (IR spectrum), one additional measurement session is carried out with an additional wavelength. At least one additional wavelength is preferably chosen to be substantially in the IR region of the electromagnetic spectrum, i.e., in the NIR-IR spectrum (having the peak emission value above 700 nm). In a preferred embodiment the use of at least three wavelengths enables the calculation of an at least one additional ratio formed by the combination of the two IR wavelengths, which is mostly dependent on changes in contact pressure or site-to-site variations. In a preferred embodiment, slight dependence of the ratio on variations in arterial oxygen saturation that may occur, is easily minimized or eliminated completely, by the proper selection and matching of the peak emission wavelengths and spectral characteristics of the at least two IR-light sources.

Preferably, the selection of the IR wavelengths is based on certain criteria. The IR wavelengths are selected to coincide with the region of the optical absorption curve where HbO_2 absorbs slightly more light than Hb. The IR wavelengths are

in the spectral regions where the extinction coefficients of both Hb and HbO_2 are nearly equal and remain relatively constant as a function of wavelength, respectively.

In a preferred embodiment, tracking changes in the ratio formed by the two IR wavelengths, in real-time, permits automatic correction of errors in the normalized ratio obtained from the R-wavelength and each of the IR-wavelengths. The term "ratio" signifies the ratio of two values of AC/DC corresponding to two different wavelengths. This is similar to adding another equation to solve a problem with at least three unknowns (i.e., the relative concentrations of HbO_2 and Hb, which are used to calculate SaO_2, and the unknown variable fraction of blood-to-tissue volumes that effects the accurate determination of SaO_2), which otherwise must rely on only two equations in the case of only two wavelengths used in conventional dual-wavelength pulse oximetry. In a preferred embodiment, a third wavelength provides the added ability to compute SaO_2 based on the ratio formed from the R-wavelength and either of the IR-wavelengths. In a preferred embodiment, changes in these ratios are tracked and compared in real-time to determine which ratio produces a more stable or less noisy signal. That ratio is used predominantly for calculating SaO_2.

The present invention utilizes collection of light reflected from the measurement location at different detection locations arranged along a closed path around light emitting elements, which can be LEDs or laser sources. Preferably, these detection locations are arranged in two concentric rings, the so-called "near" and "far" rings, around the light emitting elements. This arrangement enables optimal positioning of the detectors for high quality measurements, and enables discrimination between photodetectors receiving "good" information (i.e., AC and DC values which would result in accurate calculations of SpO_2) and "bad" information (i.e., AC and DC values which would result in inaccurate calculations of SpO_2).

There is thus provided according to one aspect of the present invention, a sensor for use in an optical measurement device for non-invasive measurements of blood parameters, the sensor comprising:

(1) a light source for illuminating a measurement location with incident light of at least three wavelengths, the first wavelength lying in a red (R) spectrum, and the at least second and third wavelengths lying substantially in the infrared (IR) spectrum; and

(2) a detector assembly for detecting light returned from the illuminated location, the detector assembly being arranged so as to define a plurality of detection locations along at least one closed path around the light source.

The term "closed path" used herein signifies a closed curve, like a ring, ellipse, or polygon, and the like.

The detector assembly is comprised of at least one array of discrete detectors (e.g., photodiodes) accommodated along at least one closed path, or at least one continuous photodetector defining the closed path.

The term "substantially IR spectrum" used herein signifies a spectrum range including near infrared and infrared regions.

According to another aspect of the present invention, there is provided a pulse oximeter utilizing a sensor constructed as defined above, and a control unit for operating the sensor and analyzing data generated thereby.

According to yet another aspect of the present invention, there is provided a method for non-invasive determination of a blood parameter, the method comprising the steps of:

illuminating a measurement location with at least three different wavelengths **λ1**, **λ2** and **λ3**, the first wavelength **λ1** lying in a red (R) spectrum, and the at least second and at least third wavelengths **λ2** and **λ3** lying substantially in the infrared (IR) spectrum;

detecting light returned from the measurement location at different detection locations and generating data indicative of the detected light, wherein said different detection locations are arranged so as to define at least one closed path around the measurement location; and

analyzing the generated data and determining the blood parameter.

BRIEF DESCRIPTION OF THE DRAWINGS

Other advantages of the present invention will be readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings wherein:

FIG. **1** illustrates hemoglobin spectra as measured by oximetry based techniques;

FIG. **2** illustrates a calibration curve used in pulse oximetry as typically programmed by the pulse oximeters manufacturers;

FIG. **3** illustrates the relative disposition of light source and detector in reflection-mode or backscatter type pulse oximetry;

FIG. **4** illustrates light propagation in reflection pulse oximetry;

FIGS. **5**A and **5**B illustrate a pulse oximeter reflectance sensor operating under ideal and practical conditions, respectively;

FIG. **6** illustrates variations of the slopes of calibration curves in reflectance pulse oximetry measurements;

FIG. **7** illustrates an optical sensor according to the invention;

FIG. **8** is a block diagram of the main components of a pulse oximeter utilizing the sensor of FIG. **7**;

FIG. **9** is a flow chart of a selection process used in the signal processing technique according to the invention; and

FIGS. **10**A to **10**C are flow charts of three main steps, respectively, of the signal processing method according to the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to the Figures, wherein like numerals indicate like or corresponding parts throughout the several views, FIGS. **1** and **2** illustrate typical hemoglobin spectra and calibrations curve utilized in the pulse oximetry measurements.

The present invention provides a sensor for use in a reflection-mode or backscatter type pulse oximeter. The relative disposition of light source and detector in the reflection-mode pulse oximeter are illustrated in FIG. **3**.

FIG. **4** shows light propagation in the reflection-mode pulse oximeter where, in addition to the optical absorption and reflection due to blood, the DC signal of the R and IR photoplethysmograms can be adversely affected by strong reflections from the bone.

FIGS. **5**A and **5**B illustrate a pulse oximeter reflectance sensor operating under, respectively, ideal and practical conditions. Referring now to FIG. **5**A, it is shown that, under

ideal conditions, reflectance sensor measures light backscattered from a homogenous mixture of blood and bloodless tissue components. Accordingly, the normalized R/IR ratio in dual-wavelength reflection type pulse oximeters, which relies on proportional changes in the AC and DC components in the photoplethysmograms, only reflect changes in arterial oxygen saturation.

Referring now to FIG. **5**B, in practical situations, the sensor applications affect the distribution of blood in the superficial layers of the skin. Accordingly, the R and IR DC signals measured by photodetectors contain a relatively larger proportion of light absorbed by and reflected from the bloodless tissue compartments. As such, the changes in DC signals depend not only on wavelength but also sensor geometry and thus cannot be eliminated completely by computing the normalized R/IR ratio, as is typically the case in dual-wavelength pulse oximeters. The result is large variations in the slope of the calibration curves, as illustrated in FIG. **6**. Referring now to FIG. **6**, graphs C**1**, C**2** and C**3** show three calibration curves, presenting the variation of the slope for oxygen saturation values between 50% and 100%.

Referring to FIG. **7**, there is illustrated an optical sensor **10** designed according to the invention aimed at minimizing some of the measurement inaccuracies in a reflectance pulse oximeter. The sensor **10** comprises such main constructional parts as a light source **12** composed of three closely spaced light emitting elements (e.g., LEDs or laser sources) **12***a,* **12***b* and **12***c* generating light of three different wavelengths, respectively; an array of discrete detectors (e.g., photodiodes), a "far" detector **16** and a "near" detector **18**, arranged in two concentric ring-like arrangements (constituting closed paths) surrounding the light emitting elements; and a light shield **14**. In the present example, six photodiodes form each ring. All these elements are accommodated in a sensor housing **17**. The light shield **14** is positioned between the photodiodes and the light emitting elements, and prevents direct optical coupling between them, thereby maximizing the fraction of backscattered light passing through the arterially perfused vascular tissue in the detected light.

It should be noted that more than three wavelengths can be utilized in the sensor. The actual numbers of wavelengths used as a light source and the number of photodetectors in each ring are not limited and depend only on the electronic circuitry inside the oximeter. The array of discrete photodiodes can be replaced by one or more continuous photodetector rings.

In addition to the R and IR light emitting elements **12***a* and **12***b* as used in the conventional pulse oximeter sensors, the sensor **10** incorporates the third, reference, light emitting element **12***c,* which emits light in the NIR-IR spectrum. Wavelength λ**1** and λ**2** of the R and IR light emitting elements **12***a* and **12***b* are centered, respectively, around the peak emission values of 660 nm and 940 nm, and wavelength λ**3** of the third light emitting element **12***c* has the peak emission value above 700 nm (typically ranging between 800 nm and 900 nm). In the description below, the light emitting elements **12***b* and **12***c* are referred to as two IR light emitting elements, and wavelengths λ**2** and λ**3** are referred to as two IR wavelengths.

During the operation of the sensor **10**, different light emitting elements are selectively operated for illuminating a measurement location (not shown) with different wavelengths. Each of the photodetectors detects reflected light of different wavelengths and generates data indicative of the intensity I of the detected light of different wavelengths.

It should be noted that the sensor can be of a compact design utilizing an integrated circuit manufactured by CMOS technology. This technique is disclosed in a co-pending application assigned to the assignee of the present application. According to this technique, the sensor comprises a package including the light source, a block of two tubular optical waveguides of different diameters concentrically dislocated one inside the other and surrounding the light source, and an integrated circuit plate comprising two ring-like areas of photodiodes positioned concentrically one inside the other. The integrated circuit is also provided with a plurality of printed contact areas and electric conductors intended for mounting the light source thereon, controlling the light source, and transmitting electric signals produced by the photodiodes areas for further processing.

FIG. **8** illustrates a block diagram of a pulse oximeter **20** utilizing the above-described sensor **10**. The pulse oximeter typically includes a control unit **21**, which is composed of an electronic block **22** including A/D and D/A converters connectable to the sensor **10**, a microprocessor **24** for analyzing measured data, and a display **26** for presenting measurement results. The measured data (i.e., electrical output of the sensor **10** indicative of the detected light) is directly processed in the block **22**, and the converted signal is further processed by the microprocessor **24**. The microprocessor **24** is operated by a suitable software model for analyzing the measured data and utilizing reference data (i.e., calibration curve stored in a memory) to compute the oxygen saturation value, which is then presented on the display **26**. The analysis of the measured data utilizes the determination of AC- and DC-components in the detected light for each wavelength, λ**1**, λ**2**, and λ**3**, respectively, i.e., $I_1^{(AC)}$, $I_1^{(DC)}$, $I_2^{(AC)}$, $I_2^{(DC)}$, $I_3^{(AC)}$, and $I_3^{(DC)}$, and the calculation of AC/DC ratio for each wavelength, namely, $W_1=I_1^{(AC)}/I_1^{(DC)}$, $W_2=I_2^{(AC)}/I_2^{(DC)}$, and $W_3=I_3^{(AC)}/I_3^{(DC)}$, as will be described more specifically further below with reference to FIGS. **9** and **10**A–**10**C.

The pulse oximeter **20** with the sensor arrangement shown in FIG. **7** provides the following three possible ratio values: W_1/W_2, W_1/W_3 and W_2/W_3. It should be noted that W_1/W_2 and W_1/W_3 are the ratios that typically have the highest sensitivity to oxygen saturation. This is due to the fact that λ**1** is chosen in the red region of the electromagnetic spectrum, where the changes in the absorption between Hb and HbO_2 are the largest, as described above with reference to FIG. **1**. Therefore, in principle, the absorption ratios formed by either wavelength pair λ**1** and λ**2** or wavelength pair λ**1** and λ**3** can be used to compute the value of SaO_2.

The inventor conducted extensive human and animal studies, and confirmed that either of the two ratios W_1/W_2 and W_1/W_3 can be affected not only by changes in arterial oxygen saturation, but also by sensor placement and by the amount of pressure applied by the sensor on the skin. Any calculation of SaO_2 based on either of the two ratios W_1/W_2 and W_1/W_3 alone (as normally done in commercially available dual-wavelength pulse oximeters) could result in significant errors. Furthermore, since at least two wavelengths are necessary for the calculation of arterial oxygen saturation, it is not feasible to self-correct the calibration curve for variations due to contact pressure or site-to-site variations utilizing the same two wavelengths used already to compute SaO_2.

The inventor has found that the third ratio W_2/W_3 formed by the combination of the two IR wavelengths is mostly dependent on changes in contact pressure or site-to-site variations. Furthermore, this ratio can depend, but to a much lesser degree, on variations in arterial oxygen saturation.

The dependency on arterial oxygen saturation, however, is easily minimized or eliminated completely, for example by selection and matching of the peak emission wavelengths and spectral characteristics of the two IR light emitting elements **12***b* and **12***c*.

Generally, the two IR wavelengths **λ2** and **λ3** are selected to coincide with the region of the optical absorption curve where HbO_2 absorbs slightly more light than Hb, but in the spectral region, respectively, where the extinction coefficients of both Hb and HbO_2 are nearly equal and remain relatively constant as a function of wavelength. For example, at 940 nm and 880 nm, the optical extinction coefficients of Hb and HbO_2 are approximately equal to 0.29 and 0.21, respectively. Therefore, ideally, the ratio of **W2**/**W3** should be close to 1, except for situations when the AC/DC signals measured from **λ2** and **λ3** are affected unequally causing the ratio **W2**/**W3** to deviate from 1.

Fortunately, variations in the ratio **W2**/**W3** mimic changes in the ratios W_1/W_2 and W_1/W_3 since these ratios are all affected by similar variations in sensor positioning or other uncontrollable factors that normally can cause large errors in the calibration curve from which oxygen saturation is typically derived. Thus, by tracking in real-time changes in the ratio formed by wavelengths **λ2** and **λ3**, it is possible to automatically correct for errors in the normalized ratios obtained from wavelengths **λ1** and **λ2**, or from **λ1** and **λ3**.

The use of an additional third wavelength in the sensor serves another important function (not available in conventional dual-wavelength pulse oximeters), which is associated with the following. Reflectance pulse oximeters have to be capable of detecting and relying on the processing of relatively low quality photoplethysmographic signals. Accordingly, electronic or optical noise can cause large inaccuracies in the final computation of SaO_2. Although the amount of electronic or optical noise pickup from the sensor can be minimized to some extent, it is impossible to render the signals measured by the pulse oximeter completely noise free. Therefore, pulse oximeters rely on the assumption that any noise picked up during the measurement would be cancelled by calculating the ratio between the R- and IR-light intensities measured by the photodetector. Practically, however, the amount of noise that is superimposed on the R- and IR-photoplethysmograms cannot be cancelled completely and, thus, can lead to significant errors in the final computation of SaO_2 which, in dual-wavelength pulse oximeters, is based only on the ratio between two wavelengths.

By utilizing a third wavelength, the invention has the added ability to compute SaO_2 based on the ratio formed from either W_1/W_2 or W_1/W_3. An algorithm utilized in the pulse oximeter according to the invention has the ability to track and compare in real-time changes between W_1/W_2 and $W_1/W_3$to determine which ratio produces a more stable or less noisy signal and selectively choose the best ratio for calculating SaO_2.

The method according to the invention utilizes the so-called "selection process" as part of the signal processing technique based on the measured data obtained with the multiple photodetectors. The main steps of the selection process are shown in FIG. **9** in a self-explanatory manner. Here, the symbol i corresponds to a single photodetector element in the array of multiple discrete photodetector elements, the term "1st" signifies the last photodetector element in the array, and the term "DATA" signify three ratios (AC/DC) computed separately for each of the three wavelengths, namely, W_1, W_2 and W_3.

The selection process is associated with the following: Practically, each time one of the light emitting elements is in its operative position (i.e., switched on), all of the photodetectors in the sensor receiving backscattered light from the skin. However, the intensity of the backscattered light measured by each photodetector may be different from that measured by the other photodetectors, depending on the anatomical structures underneath the sensor and its orientation relative to these structures.

Thus, the selection process is used to discriminate between photodetectors receiving "good" signals (i.e., "good" signal meaning that the calculation of SpO_2 from the pulsating portion of the electro-optic signal (AC) and the constant portion (DC) would result in accurate value) and "bad" signals (i.e., having AC and DC values which would result in inaccurate calculations of SpO_2). Accordingly, each data point (i.e., ratio W_{1i}, W_{2i} or W_{3i} detected at the corresponding i^{th} detector) is either accepted, if it meets a certain criteria based for example on a certain ratio of AC to DC values (e.g., such that the intensity of AC signal is about 0.05–2.0% of the intensity of DC signal), or rejected. All of the accepted data points (data from accepted detection locations) are then used to calculate the ratios W_1/W_2, W_1/W_3 and W_2/W_3, and to calculate the SpO_2 value, in conjunction with the signal processing technique, as will be described further below with reference to FIGS. **10**A–**10**C.

Besides the use of the third IR-wavelength to compensate for changes in the internal calibration curve of the pulse oximeter, the pulse oximeter utilizing the sensor according to the invention provides a unique new method to compensate for errors due to sensor positioning and pressure variability. This method is based on multiple photodetector elements, instead of the conventional approach that relies on a single photodetector.

While optical sensors with multiple photodetectors for application in reflectance pulse oximetry have been described before, their main limitation relates to the way the information derived from these photodetectors is processed. Although the primary purpose of utilizing multiple photodetectors is to collect a larger portion of the backscattered light from the skin, practically, summing the individual intensities of each photodetector and using the resulting value to compute SaO_2 can introduce large errors into the calculations. These errors can be caused, for example, by situations where the sensor is placed over inhomogeneous tissue structures such as when the sensor is mounted on the chest. The case may be such that, when using a continuous photodetector ring to collect the backscattered light, a portion of the photodetector ring lies over a rib, which acts as a strongly reflecting structure that contributes to a strong DC component, and the remaining part of the photodetector is positioned over the intercostals space, where the DC signal is much smaller. In this case, the final calculation of SaO_2 would be inaccurate, if the current produced by this photodetector is used indiscriminately to compute the DC value before the final computation of SaO_2 is performed. Therefore, in addition to automatically correcting errors in the calibration curve as outlined above using three different LEDs (one R and two different IR wavelengths), the sensor **10** has the optional ability to track automatically and compare changes in the R/IR ratios obtained from each of the discrete photodiodes individually. For example, if some of either the near or the far photodetectors in the two concentrically arranged arrays detect larger than normal DC signals during the operation of one of the photodiodes compared to the other photodiodes in the sensor, it could be indicative of one of the following situations: the sensor is positioned

unevenly, the sensor is partially covering a bony structure, or uneven pressure is exerted by the sensor on the skin causing partial skin "blanching" and therefore the blood-to-bloodless tissue ratio might be too high to allow accurate determination of SaO_2. If such a situation is detected, the oximeter has the ability to selectively disregard the readings obtained from the corresponding photodetectors. Otherwise, if the DC and AC signals measured from each photodetector in the array are similar in magnitude, which is an indication that the sensor is positioned over a homogeneous area on the skin, the final computation of SaO_2 can be based on equal contributions from every photodetector in the array.

Turning now to FIGS. **10**A, **10**B and **10**C, there are illustrated three main steps of the signal processing technique utilized in the present invention Here, TH_1 and TH_2 are two different threshold values (determined experimentally) related respectively to W_2/W_3 and $(W_1/W_2-W_1/W_3)$.

During step **1** (FIG. **10**A), measured data generated by the "near" and "far" photodetectors indicative of the detected (backscattered) light of wavelength **λ2** and **λ3** is analyzed to calculate the two ratios W_2/W_3 (far and near). If one of the calculated ratios (far or near) is not in the range of $1\pm TH_1$ (TH_1 is for example 0.1), then this data point is rejected from the SpO_2 calculation, but if both of them are not in the mentioned range, a corresponding alarm is generated indicative of that the sensor position should be adjusted. Only if there are calculated ratios which are in the range of 1±TH**1**, they are accepted and the process (data analysis) proceeds by performing step **2**.

Step **2** (FIG. **10**B) consists of determining whether the quality of each photoplethysmogram is acceptable or not. The quality determination is based on the relative magnitude of each AC component compared to its corresponding DC component. If the quality is not acceptable (e.g., the signal shape detected by any detector varies within a time frame of the measurement session, which may for example be 3.5 sec), the data point is rejected and a corresponding alarm signal is generated. If the AC/DC ratio of W_1, W_2 and W_3 are within an acceptable range, the respective data point is accepted, and the process proceeds through performing step **3**.

In step **3** (FIG. **10**C), the measured data is analyzed to calculate ratios W_1/W_2 and W_1/W_3 from data generated by far and near photodetectors, and to calculate the differences $(W_1/W_2-W_1/W_3)$.

In a perfect situation, W_1/W_2 (far) is very close to W_1/W_3 (far), and W_1/W_2 (near) is very close to W_1/W_3 (near). In a practical situation, this condition is not precisely satisfied, but all the ratios are close to each other if the measurement situation is "good".

Then, the calculated differences are analyzed to determine the values (corresponding to far and near photodetectors) that are accepted and to use them in the SpO_2 calculation. For each detector that satisfied the condition $ABS(W_1/W_2-W_1/W_3)<TH_2$), where ABS signifies the absolute value, its respective data point is accepted and used to calculate the oxygen saturation value that will be displayed. If the condition is not satisfied, the data point is rejected. If all data points are rejected, another measurement session is carried out.

It should be noted that, although the steps **1–3** above are exemplified with respect to signal detection by both near and far photodetectors, each of these steps can be implemented by utilizing only one array of detection locations along the closed path. The provision of two such arrays, however, provides higher accuracy of measurements.

ELEMENT LIST
10 optical sensor
12 light source
12*a* LED
12*b* LED
12*c* LED
13 detector assembly
14 light shield
15 array of detectors
16 far detector
17 sensor housing
18 near detector
20 pulse oximeter
21 control unit
22 electronic block
24 microprocessor
26 display

What is claimed is:

1. A method for non-invasive determination of a blood parameter, the method comprising the steps of:

(i) illuminating a measurement location with at least three different wavelenths, a first wavelength **λ1** lying in a red (R) spectrum, and at least second and third wavelengths **λ2** and **λ3** lying substantially in the infrared (IR) spectrum;

(ii) detecting light returned from the measurement location at different detection locations and generating data indicative of the detected light for the different detection locations, wherein said different detection locations are arranged so as to define at least one closed path around the measurement location; and

(iii) analyzing the generated data and determining the blood parameter.

2. The method according to claim **1**, wherein the analysis of the generated data comprises the steps of:

calculating data indicative of an AC/DC ratio in the light detected at each of the detection locations for the at least three wavelengths;

analyzing the calculated data and determining accepted detection locations to select corresponding AC/DC ratios for each of the at least three wavelengths, **λ1**, **λ2** and **λ3**; and

utilizing the selected ratios for determining the blood parameter.

3. The method according to claim **2**, wherein the determination of the blood parameter comprises the steps of:

calculating values of the ratio W_2/W_3 for the accepted detection locations in at least one closed path;

analyzing each of the calculated values to determine whether it satisfies a first predetermined condition, so as to generate a signal indicative of that a sensor position is to be adjusted, if the condition is not satisfied;

if the condition is satisfied, determining whether the quality of a photoplethysmogram is acceptable;

if the quality is acceptable, analyzing the selected ratios for calculating ratios W_1/W_2 and W_1/W_3 from the data detected in at least one closed path, and calculating the differences $ABS(W_1/W_2-W_1/W_3)$; and,

analyzing the calculated differences for determining whether each of the differences satisfies a second predetermined condition for determining the blood parameter if the condition is satisfied.

4. The method according to claim **3**, wherein said first predetermined condition consists of that the calculated value

of W2/W3 is inside a predetermined range around the value one, said predeteonined range being defined by the first threshold value, and the second predetermined condition consists of that the calculated difference ABS (W1/W2−W1/W3) is less than certain, second threshold value.

5. A method for non-invasive determination of a blood parameter, the method comprising the steps of:

illuminating a measurement location with at least three different wavelengths, a first wavelength λ1 lying in a red (R) spectrum, and at least second and third wavelengths λ2 and λ3 lying substantially in the infrared (IR) spectrum;

detecting light returned from the measurement location at different detection locations and generating data indicative of the detected light for the different detection locations, wherein said different detection locations are arranged so as to define at least one closed path around the measurement location;

calculating data indicative of an AC/DC ratio in the light detected at each of the detection locations for the at least three wavelengths; and,

analyzing the calculated data and determining the blood parameter.

* * * * *

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	Poeze et al.	
U.S. Patent No.:	10,702,194	Attorney Docket No.: 50095-0025IP1
Issue Date:	July 7, 2020	
Appl. Serial No.:	16/829,536	
Filing Date:	Mar. 25, 2020	
Title:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS	

SECOND DECLARATION OF DR. THOMAS W. KENNY

I hereby declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true. I further declare that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of the Title 18 of the United States Code.

Dated: November 1, 2021

By: ________________________

Thomas W. Kenny, Ph.D.

APPLE 1060
Apple v. Masimo
IPR2020-01716

compensation is not dependent on the outcome of these proceedings or the content of my opinions.

5. In writing this declaration, I have considered the following: my own knowledge and experience, including my work experience in the fields of mechanical engineering, computer science, biomedical engineering, and electrical engineer; my experience in teaching those subjects; and my experience in working with others involved in those fields. In addition, I have analyzed various publications and materials, in addition to other materials I cite in my declaration.

6. My opinions, as explained below, are based on my education, experience, and expertise in the fields relating to the '194 Patent. Unless otherwise stated, my testimony below refers to the knowledge of one of ordinary skill in the fields as of the Critical Date, or before.

II. Ground 1

7. As I explained at length in my first declaration, a POSITA "would have found it obvious to modify the [Aizawa] sensor's flat cover…to include a lens/protrusion…similar to Ohsaki's translucent board 8, so as to [1] improve adhesion between the user's wrist and the sensor's surface, [2] improve detection efficiency, [3] and protect the elements within the sensor housing." APPLE-1003, ¶¶78-83. Rather than attempting to rebut my testimony on these points, Masimo and its witness, Dr. Madisetti, responded with arguments that are technically and factually flawed.

8. Specifically, Masimo contends that "Ohsaki and Aizawa employ different sensor structures (rectangular versus circular) for different measurement locations (back side versus palm side of the wrist), using different sensor surface shapes (convex versus flat) that are tailored to those specific measurement locations" and from this concludes that "[a] POSITA would [not] have been motivated to combine the references and reasonably expected such a combination to be successful." IPR2020-01716, Pap. 15 ("**POR**"), 1-3.

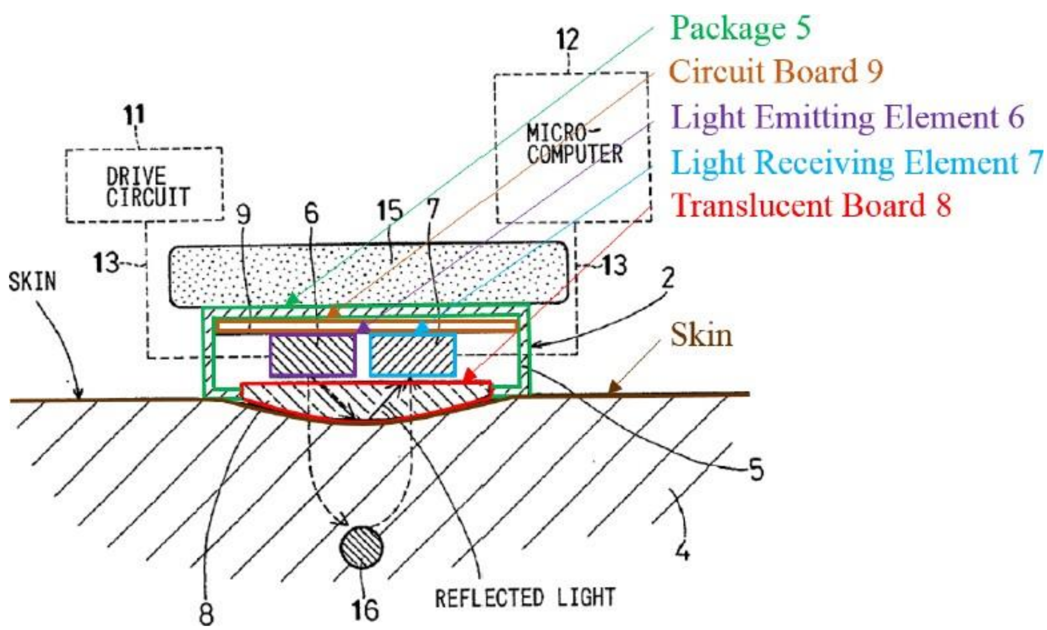
9. In this way and as I explain in further detail, the POR avoids addressing the merits of the combinations advanced in Apple's Petition, relies on mischaracterizing the prior art combinations and my testimony, and ignores the inferences and creative steps that a POSITA would have taken when modifying Aizawa's sensor to achieve the benefits taught by Ohsaki and Mendelson-2003, among others.

10. Contrary to Masimo's contentions, Ohsaki does not limit its benefits to a rectangular sensor applied to a particular body location, and a POSITA would not have understood those benefits as being so limited. For example, Ohsaki teaches that "the detecting element and the sensor body 3 may be worn on the back side of the user's forearm" or wrist. Nowhere does Ohsaki teach that its sensor can only be worn on a particular body location. APPLE-1014, [0030], [0008]-[0010], Abstract. In its summary of invention and claim preambles, Ohsaki explains that the object of its invention is "to provide a human pulse wave sensor which is capable of detecting the pulse wave ***of a human body*** stably and has high detection probability." APPLE-

1014, [0007], claims 1-8. Thus, Ohsaki's disclosure should not be narrowly understood as applying to a single location or a single embodiment. Aizawa similarly reveals an embodiment in which its sensor is located on the palm side of the wrist (*see* APPLE-1006, FIG. 2, [0002], [0009]), but does not limit its sensor to being applied to just the palm side of the wrist. A POSITA, based on Aizawa and Ohsaki's disclosure, would have understood that the sensors in Aizawa and Ohsaki, when combined in the manner explained in my earlier declaration, would have been applicable to various locations on a human body and would have improved the performance of the sensor by providing the benefits described in these disclosures. Indeed, a POSITA would understand that the claimed benefits of the detector arrangement and the convex cover would have been useful and beneficial for measurements on many other locations.

11. In addition to the above, as shown in Ohsaki's FIG. 2 (reproduced below), Ohsaki attributes the reduction of slippage afforded by use of translucent board 8 (and additional related improvements in signal quality) to the fact that "***the convex surface of the translucent board…is in intimate contact with the surface of the user's skin***"[1] when the sensor is worn. APPLE-1003, ¶76; APPLE-1014, [0015], [0017], [0025], FIGS. 1, 2, 4A, 4B.

[1] Unless otherwise noted, emphases in quotations throughout my declaration are added.



APPLE-1014, FIG. 2 (annotated).

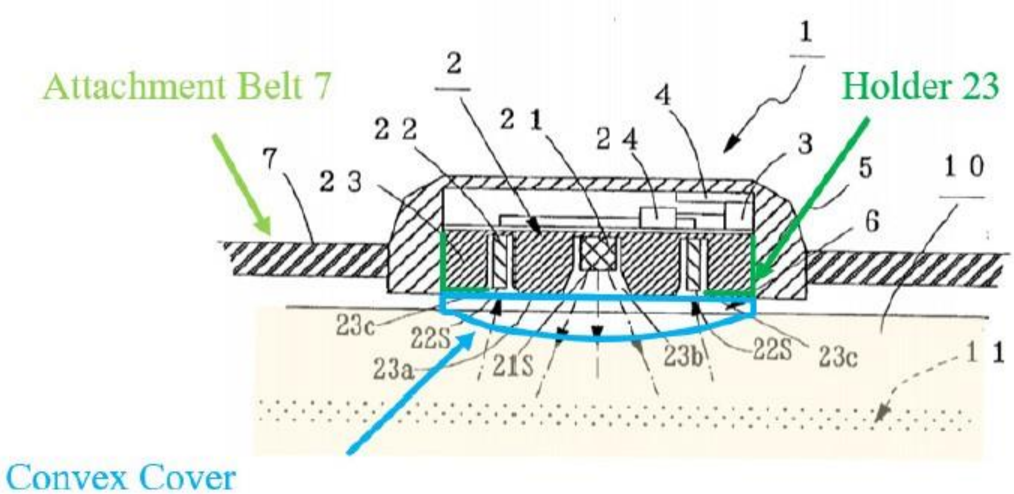
12. Notably absent from Ohsaki's discussion of these benefits is any mention or suggestion that they relate to the shape of the perimeter of translucent board 8 (whether circular, rectangular, ovoid, or other). Rather, when describing the advantages associated with translucent board 8, Ohsaki contrasts a "convex detecting surface" from a "flat detecting surface," and explains that "if the translucent board 8 has a flat surface, the detected pulse wave is adversely affected by the movement of the user's wrist," but that ***if the board "has a convex surface…variation of the amount of the reflected light…that reaches the light receiving element 7 is suppressed***." APPLE-1003, ¶77; APPLE-1014, [0015], [0025].

13. From this and related description, a POSITA would have understood that a protruding convex cover would reduce the adverse effects of user movement on signals obtainable by photodetectors which are positioned to detect light reflected

from user tissue. APPLE-1003, ¶¶77-79; APPLE-1014, [0015], [0017], [0025], FIGS. 1, 2, 4A, 4B; *see also* APPLE-1006, [0012], [0013], [0023], [0024], [0026], [0030], [0034], FIGS. 1(a), 1(b). A POSITA would expect that these benefits would apply to the pulse wave sensor of Aizawa, as well as to other wearable physiological monitors.

14. In addition, as I explain with respect to the prior art figures reproduced below, the POSITA would have found it obvious to improve Aizawa's sensor based on Ohsaki's teachings, and would have been fully capable of making any inferences and creative steps necessary to achieve the benefits obtainable by modifying Aizawa's cover to feature a convex detecting surface.[2] *See also* APPLE-1008, ¶¶14-15, FIG. 1. The following annotated FIG. 1(b) from Aizawa shows the results of the proposed combination:

[2] Nowhere in Ohsaki is the cover depicted or described as rectangular. APPLE-1014, [0001]-[0030]; FIGS. 1, 2, 3A, 3B, 4A, 4B.



APPLE-1006, FIG. 1(b)(annotated)

15. And, contrary to Masimo's contentions, the POSITA would have in no way been dissuaded from achieving those benefits by a specific body location associated with Ohsaki's sensor. POR, 34-46. Indeed, a POSITA would have understood that a light permeable convex cover would have provided improved adhesion as described by Ohsaki in a sensor placed, for example, on the palm side of the wrist or other locations on the body. APPLE-1014, [0025], Claim 3 (stating that "the detecting element is constructed to be worn on a user's wrist or a user's forearm" without specifying a back or front of the wrist or forearm), FIGS 4A, 4B; *see also* APPLE-1023, 91.

16. A POSITA would also have understood that certain locations present anatomical features that provide for easy measurement of large reflected light signals and other locations present anatomical features that reduce the amplitude of the reflected light signals. Because of this, a POSITA would be motivated to search for features from other references that can provide improved adhesion, improved light

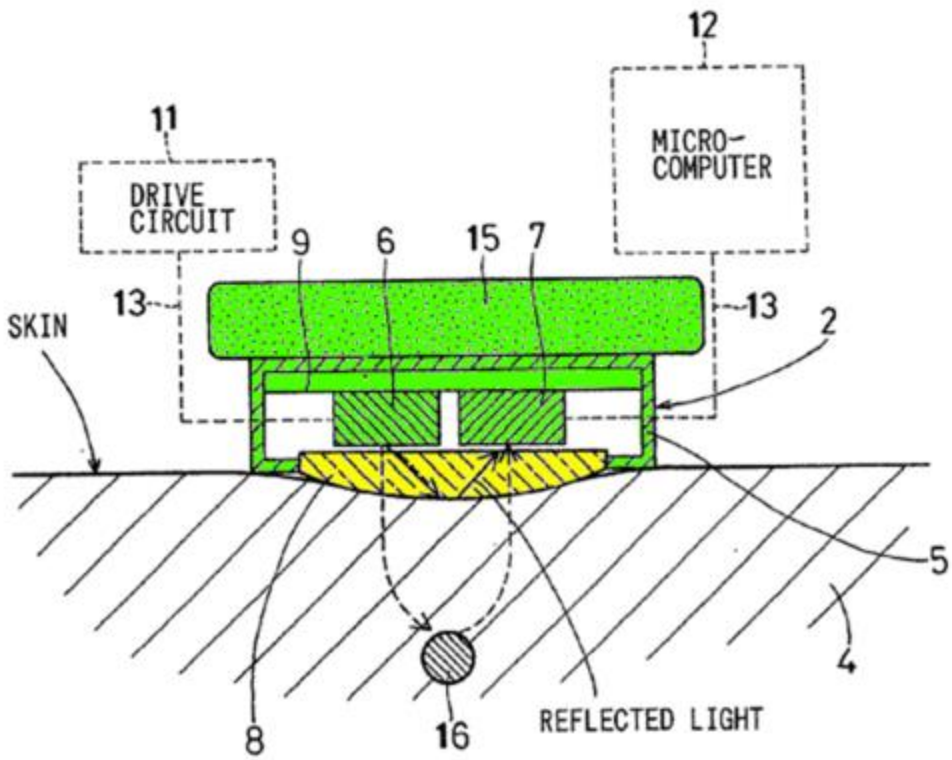
gathering, reduced leakage of light from external sources, and protection of the elements within the system in order to successfully detect a pulse wave signal from many locations.

17. For these and other reasons explained below, Masimo's arguments should be rejected. The sections below address the arguments with respect to Ground 1 presented in Masimo's POR and explain, in more detail, why those arguments fail.

A. Ohsaki does not teach or require that its translucent board 8 is "rectangular" in shape

18. In my first declaration, I explained that a POSITA would have modified Aizawa in view of Ohsaki such that Aizawa's cover "would include a convex surface, improving adhesion between a subject's wrist and a surface of the sensor." APPLE-1003, ¶78 (citing APPLE 1009, [0025] Ohsaki explains that the "convex surface of the translucent board 8" is responsible for this improved adhesion). Masimo argues that it is not the "convex surface" that improves adhesion in Ohsaki, but instead the "longitudinal shape" of "Ohsaki's translucent board [8]." *See* POR, 13, 25-31 (citing APPLE-1014, [0019]). However, the portion of Ohsaki cited does not include any reference to board 8. *See* APPLE-1014, [0019]. Ohsaki does ascribe a "longitudinal" shape to a different component: "detecting element 2." *See id*. Ohsaki never describes the "translucent board 8" as "longitudinal," and nowhere describes "translucent board 8" and "detecting element 2" as having the same shape. *See generally* APPLE-1014. In fact, as illustrated in Ohsaki's FIG. 2 (reproduced below),

translucent board 8 (annotated yellow) is not coextensive with the entire tissue-facing side of detecting element 2 (annotated green).

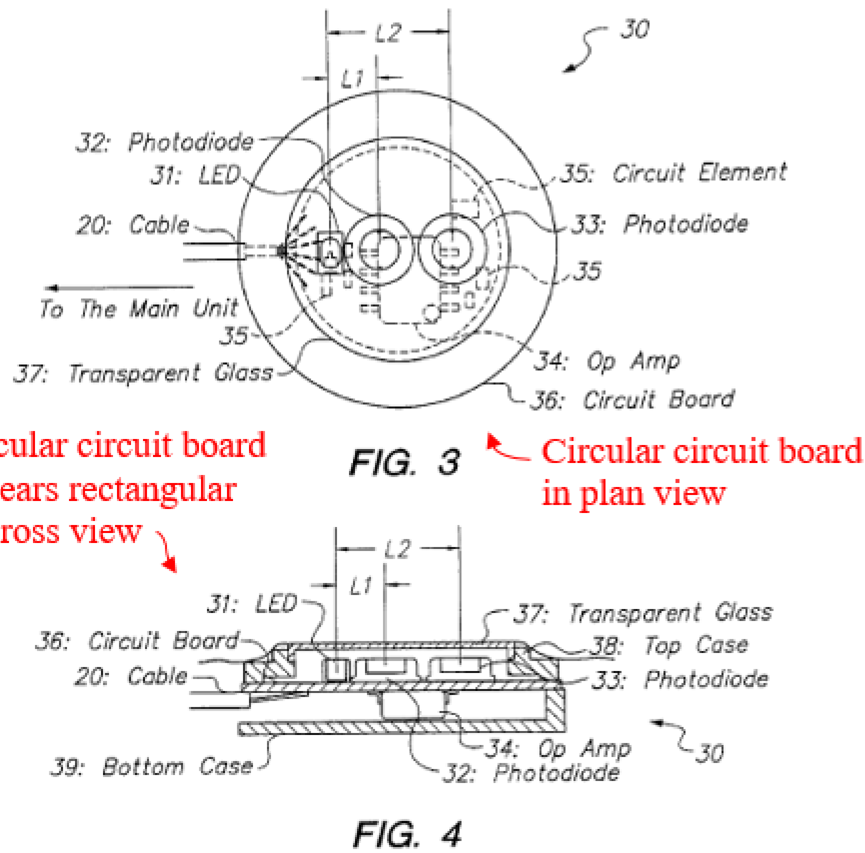


APPLE-1014, FIG. 2 (annotated)

19. Based on the unsupported contention that translucent board 8 has a "very pronounced longitudinal directionality," Masimo concludes that the translucent board 8 has a "rectangular" shape that is allegedly incompatible with Aizawa. But Ohsaki never describes translucent board 8, or any other component, as "rectangular"; in fact, the words "rectangular" and "rectangle" do not appear in Ohsaki's disclosure. *See generally* APPLE-1014.

20. Indeed, the POR incorrectly assumes that because Ohsaki's light emitting

element and the light receiving element are arranged in a longitudinal structure, Ohsaki's translucent board must have a rectangular structure. APPLE-1014, [0009], [0019]; POR, 18-19. Yet a POSITA would have known and understood that an elliptical or circular sensor or board configuration can also have a longitudinal structure or appearance under a cross-sectional view. An example illustrating such an understanding, ***contrary to POR's flawed assumption***, is shown below in US Patent No. 6,198,951 ("Kosuda")'s FIGS. 3 and 4. APPLE-1010, 8:42-56.



APPLE-1010, FIGS 3 and 4

21. Attempting to confirm its false conclusion, Masimo asserts that "***Ohsaki illustrates two cross-sectional views*** of its board that confirm it is rectangular." POR,

18 (citing Ex. 2004, [39]-[42]). Masimo identifies these "two cross-sectional views" as FIGS. 1 and 2, and infers the supposed "rectangular shape" of the translucent board 8 based on FIG. 1 showing the "short" side of the device, and FIG. 2 showing the "long" side of the same device. *See* POR, 18-20. But, according to Ohsaki, FIG. 2 is "a schematic diagram," not a cross-sectional view, and Ohsaki never specifies that FIGS. 1 and 2 are different views of the same device. APPLE-1014, [0013]. Accordingly, nothing in Ohsaki supports Masimo's inference that the "translucent board 8" ***must be*** "rectangular" in shape. *See, e.g.,* APPLE-1014, [0013], [0019], [0025], FIG. 2. Further, even if it is possible for the translucent board 8 to be "rectangular," Ohsaki certainly does not teach nor include any disclosure "***requiring***" this particular shape. *Id.*

22. The POR presents multiple arguments with respect to Ground 1 that are premised on Ohsaki ***requiring*** the translucent board 8 to be "rectangular." Because Ohsaki discloses no such shape for the translucent board 8, these arguments fail.

23. In addition, as discussed above, even if Ohsaki's translucent board 8 were somehow understood to be rectangular, a POSITA would have been fully capable of modifying Aizawa to feature a light permeable protruding convex cover to obtain the benefits attributed to such a cover by Ohsaki. For example, a POSITA would have found it obvious to include a circular light-permeable convex cover based on the teachings of Ohsaki, and take reasonable steps to make sure that the combination of a circular protruding convex cover would function with the other features present in

Aizawa so as to provide the benefits discussed above.

B. A POSITA would have recognized the benefits of Ohsaki's teachings when applied to Aizawa's sensor

24. Masimo contends that "Ohsaki indicates that its sensor's convex board ***only*** improves adhesion when used on the ***back*** (i.e., watch) side of the wrist," and that "Aizawa ***requires*** its sensor be positioned on the palm side of the wrist," and therefore reaches a conclusion that "[a] POSITA seeking to improve adhesion of Aizawa's sensor would not incorporate a feature that only improves adhesion at a different and unsuitable measurement location." POR, 34. But Ohsaki does not describe that its sensor can ***only*** be used at a backside of the wrist, and Aizawa never requires that its sensor be positioned on the palm side of the wrist. Instead, at most, these disclosures simply describe these arrangements with respect to a preferred embodiment. APPLE-1014, [0019].

25. Indeed, Ohsaki's specification and claim language reinforce that Ohsaki's description would not have been understood as limited to one side of the wrist. For example, Ohsaki explains that "the detecting element 2…may be worn on the back side of the user's forearm" as one form of modification. *See* APPLE-1014, [0030], [0028] (providing a section titled "[m]odifications"). The gap between the ulna and radius bones at the forearm is even greater than the gap between bones at the wrist, which is already wide enough to easily accommodate a range of sensor sizes and shapes, including circular shapes. In addition, Ohsaki's claim 1 states that "the

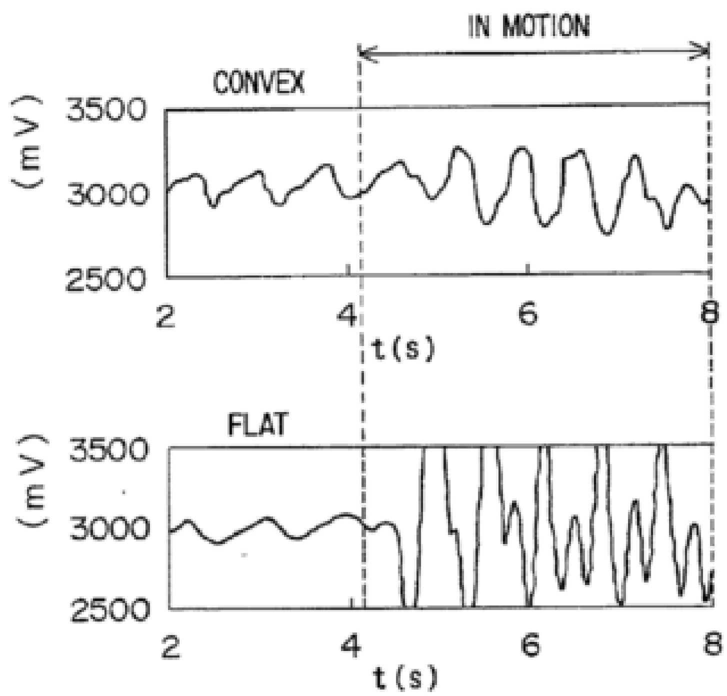
detecting element is constructed to be worn on a back side of a user's wrist ***or a user's forearm***." *See also* APPLE-1014, claims 1-2. As another example, Ohsaki's independent claim 5 and dependent claim 6 state that "the detecting element is constructed to be worn on a user's wrist or a user's forearm," ***without even mentioning a backside*** of the wrist or forearm. *See also* APPLE-1014, Claims 6-8. A POSITA would have understood this language to directly contradict Masimo's assertion that "[t]o obtain any benefit from Ohsaki's board, the sensor must be positioned on the backhand side of the wrist." POR, 25. A POSITA would have understood that Ohsaki's benefits provide improvements when the sensor is placed on either side of the user's wrist or forearm. APPLE-1014, [0025], FIGS. 4A, 4B.

26. POR presents several arguments with respect to Ground 1 that are premised on Ohsaki ***requiring*** the detecting element to be worn on a back side of a user's wrist or a user's forearm. Because Ohsaki requires no such location for the translucent board 8, these arguments fail.

27. Moreover, even assuming, for the sake of argument, that a POSITA would have understood Aizawa's sensor as being limited to placement on the backside of the wrist, and would have understood Ohsaki's sensor's "tendency to slip" when arranged on the front side as informing consideration of Ohsaki's teachings with respect to Aizawa, that ***would have further motivated*** the POSITA to implement a light permeable convex cover in Aizawa's sensor, to improve detection efficiency of that sensor when placed on the palm side. APPLE-1014, [0015], [0017], [0023],

[0025], FIGS. 1, 2, 3A, 3B, 4A, 4B.

28. When describing advantages associated with its translucent board, Ohsaki explains with reference to FIGS. 4A and 4B (reproduced below) that "if the translucent board 8 has a flat surface, the detected pulse wave is adversely affected by the movement of the user's wrist," but that if the board "has a convex surface…variation of the amount of the reflected light…that reaches the light receiving element 7 is suppressed." APPLE-1003, ¶¶77-78; APPLE-1014, [0015], [0017], [0025].



APPLE-1014, FIGS. 4A, 4B

29. Contrary to Masimo's contentions, a POSITA would not have understood these benefits of a convex surface over a flat surface to be limited to one side or the other of the user's wrist, or to any particular location. APPLE-1014, [0023]-[0025]. Rather, a POSITA would have understood that, by promoting "intimate contact with

the surface of the user's skin," a light permeable convex cover would have increased adhesion and reduced slippage of Aizawa's sensor when placed on either side of a user's wrist or forearm, and additionally would have provided associated improvements in signal quality. APPLE-1014, [0015], [0017], [0025]; FIGS. 1, 2, 4A, 4B, claims 3-8; *see also* APPLE-1023, 87, 91. Indeed, a POSITA would have recognized that modifying Aizawa's flat plate to feature a convex protruding surface, as taught by Ohsaki, would have furthered Aizawa's stated goal of "improv[ing] adhesion between the sensor and the wrist" to "thereby further improve the detection efficiency." APPLE-1006, [0013], [0026], [0030], [0034].

30. Further, the POSITA would have been fully capable of employing inferences and creative steps when improving Aizawa based on Ohsaki's teachings, and would have expected success when applying those teachings. Indeed, a POSITA would have understood that adding a convex protrusion to Aizawa's flat plate would have provided an additional adhesive effect that would have reduced the tendency of that plate to slip. Among other things, it is well understood that physically extending into the tissue and displacing the tissue with a protrusion will provide an additional adhesive/gripping effect.

C. Modifying Aizawa's sensor to include a convex cover as taught by Ohsaki enhances the sensor's light-gathering ability

31. Masimo argues that the combined sensor "would direct light away from the detectors and thus decrease light collection and optical signal strength." *See, e.g.*,

POR, 47-53. As explained below, a POSITA would have understood the opposite to be true—that a cover featuring a convex protrusion would improve Aizawa's signal-to-noise ratio by causing more light backscattered from tissue to strike Aizawa's photodetectors than would have with a flat cover. APPLE-1023, 52, 86, 90; APPLE-1061, 84, 87-92, 135-141; APPLE-1017, 803-805; APPLE-1006, FIGS. 1(a)-1(b). The convex cover enhances the light-gathering ability of Aizawa's sensor.

32. Masimo and its witness, Dr. Madisetti, assert that "a POSITA would have believed that a convex surface would…direct[] light away from the periphery and towards the center of the sensor." In so doing, POR and Dr. Madisetti fail to articulate a coherent position—e.g., whether Masimo's position is that "all" light or only "some" light is directed "to" or "towards the center." POR, 25, 50-54, Ex. 2004, ¶¶90-98.

33. For example, Dr. Madisetti testified during deposition in one of the various related cases to this patent that "as I describe in my Declaration...if you have a convex surface...***all light*** reflected or otherwise would be condensed or directed towards the center." APPLE-1054, 40:4-11; *see also id.*, 127:22-128:18; Ex. 2004, ¶87 ("A POSITA Would Have Understood That a Convex Cover Directs Light ***To The Center*** Of The Sensor"). However, during the same deposition, Dr. Madisetti further stated that that a convex cover would redirect light "towards the center," which could be "a general area at which the convex surface would be redirecting…light" or "a

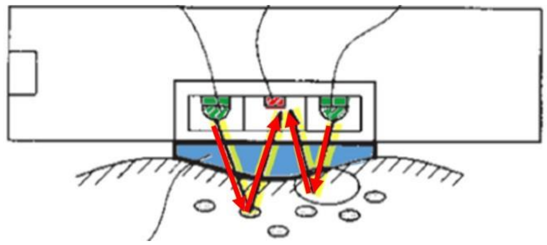
point," while contrasting the phrase "to the center" from "towards the center." APPLE-1054, 105:12-107:1, 133:19-135:11.

34. In contrast, and as explained in more detail below, I have consistently testified that a POSITA would have understood that a convex cover improves "light concentration at pretty much ***all of the locations under the curvature of the lens***," and for at least that reason would have been motivated to modify Aizawa's sensor to include a convex cover as taught by Ohsaki. Ex. 2006, 164:8-16.

i. Masimo ignores the well-known principle of reversibility

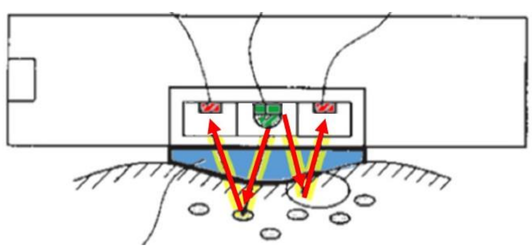
35. The well-known optical ***principle of reversibility*** dispels Masimo's claim that "a convex cover condenses light towards the center of the sensor and away from the periphery," when applied to Aizawa. POR, 47; APPLE-1061, 87-92; APPLE-1062, 106-111. According to the principle of reversibility, "a ray going from P to S will trace the same route as one from S to P." APPLE-1061, 92, 84; APPLE-1062, 101, 110; APPLE-1053, 80:20-82:20. Importantly, the principle dictates that rays that are not completely absorbed by user tissue will propagate in a reversible manner. In other words, every ray that completes a path through tissue from an LED to a detector would trace an identical path through that tissue in reverse, if the positions of the LED emitting the ray and the receiving detector were swapped. APPLE-1061, 92. To help explain, I have annotated Inokawa's FIG. 2 (presented below) to illustrate the principle of reversibility applied in the context of a reflective optical physiological

monitor. As shown, Inokawa's FIG. 2, illustrates two example ray paths from surrounding LEDs (green) to a central detector (red):



APPLE-1008, FIG. 2 (annotated)

36. As a consequence of the principle of reversibility, a POSITA would have understood that if the LED/detector configuration were swapped, as in Aizawa, the two example rays would travel identical paths in reverse, from a central LED (red) to surrounding detectors (green). A POSITA would have understood that, for these rays, any condensing/directing/focusing benefit achieved by Inokawa's cover (blue) under the original configuration would be identically achieved under the reversed configuration:



APPLE-1008, FIG. 2 (annotated)

37. When factoring in additional scattering that may occur when light is reflected within human tissue, reversibility holds for each of the rays that are not completely absorbed; consequently, "if we're concerned with the impact of the lens on the system, it's absolutely reversible." APPLE-1059, 209:19-21, 207:9-209:21 ("one

could look at any particular randomly scattered path…and the reversibility principle applies to all of the pieces [of that path] and, therefore, applies to the aggregate").

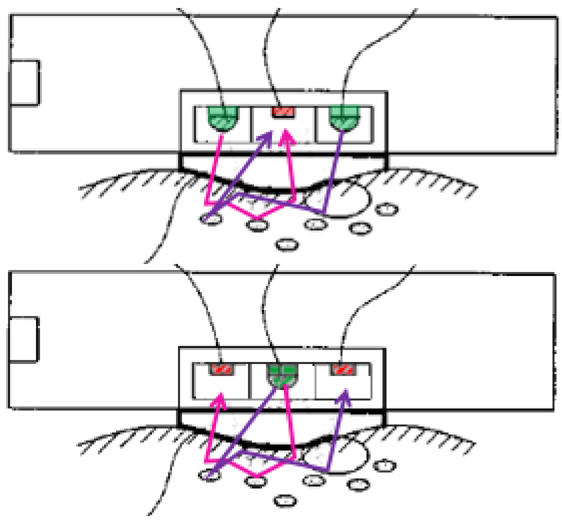
38. An example of reversibility in a situation with diffuse light, such as is present when LEDs illuminate tissue, is shown below from Hecht's Figure 4.12.

Figure 4.12 (a) Specular reflection. (b) Diffuse reflection. (Photos courtesy Donald Dunitz.)

39. In this figure 4.12a, collimated light is incident on a smooth surface, and exhibits specular reflection, in which parallel light rays encounter and are reflected from the surface and remain parallel. A POSITA would certainly understand specular reflection. In the case of the reflection as shown in Figure 4.12b, the random roughness of the surface scatters the incoming rays into many directions, and the resulting light would appear to be diffuse. However, even in this circumstance, the principle of reversibility applies–each individual ray can be reversed such that a ray travelling to the surface and scattered in a random direction can be followed backwards along exactly the same path.

40. In more detail, and as shown with respect to the example paths illustrated below (which include scattering within tissue), each of the countless photons

travelling through the system must abide by Fermat's principle. APPLE-1062, 106-111. Consequently, even when accounting for various random redirections and partial absorptions, each photon traveling between a detector and an LED would take the quickest (and identical) path along the segments between each scattering event, even if the positions of the detector and LED were swapped.



41. To better understand the effect of a convex lens on the propagation of light rays towards or away from the different LEDs or detectors, the first and last segment of the light path may be representative of the light propagation of the various light rays. In the figures above, starting at the upper left, there is a pink-colored light ray emerging from the green LED and passing through the convex lens and entering the tissue. On the lower left, there is a pink-colored light ray leaving the tissue and entering the convex lens. As drawn, these rays are the same in position and orientation, except that the direction is exactly reversed. This illustration is consistent with the Principle of Reversibility as applied to this pair of possible light

rays. According to the principle of reversibility, the upper light path from the LED to the first interaction with a corpuscle is exactly reversed. This same behavioral pattern applies to all of the segments of the many light paths that cross the interface at the surface of the convex lens. Importantly, in this example, the convex lens does not refract the incoming ray in a different direction from the outgoing ray, e.g., in a direction towards the center different from the outgoing ray. As required by the principle of reversibility, this incoming ray follows the same path as the outgoing ray, except in the reverse direction. This statement is true for every segment of these light paths that crosses the interface between the tissue and the convex lens. Any ray of light that successfully traverses a path from the LED to the detector, that path already accounts for the random scattering as that scattering is what allowed the ray to go from the LED to a detector along the path to thereby be subsequently detected by the detector. A POSITA would have understood that the path is an aggregation of multiple segments and that the path is reversible as each of its segments would be reversible, consistent with Fermat's principle.

42. The statement about the reversibility of the segments of the light path which cross the interface between tissue and convex lens is consistent with the well-known and well-established Snell's law, which provides a simple algebraic relation between the angles of incidence and refraction as determined by the two indices of refraction. And Snell's law supports the basic understanding that the path of the light rays to/from a scattering event across the interface to/from the convex lens and on to/from

the LED or photodetector must be reversible.

43. Based on this understanding of light rays and Snell's law, a POSITA would have understood that the positions of the emitters and detectors can be swapped in the proposed combination, and that the light paths from the initial situation would be reversed in the altered situation.

44. When confronted with this basic principle of reversibility during deposition, Dr. Madisetti refused to acknowledge it, even going so far as to express ignorance of "Fermat's principle, ***whatever that is***." APPLE-1054, 89:12-19. Yet Fermat's principle, which states that a path taken by a light ray between two points is one that can be traveled in the least time, regardless of the direction of travel, is one of the most fundamental concepts in optics/physics and plainly requires the basic principle of reversibility. APPLE-1061, 87-92; APPLE-1062, 106-111. This is in no way a new theory, as this core concept dates back many years, and is offered in Aizawa itself. Indeed, ***Aizawa recognizes this reversibility***, stating that while the configurations depicted include a central emitter surrounded by detectors, the "same effect can be obtained when…a plurality of light emitting diodes 21 are disposed around the photodetector 22." APPLE-1006, [0033]; APPLE-1059, 209:19-21.

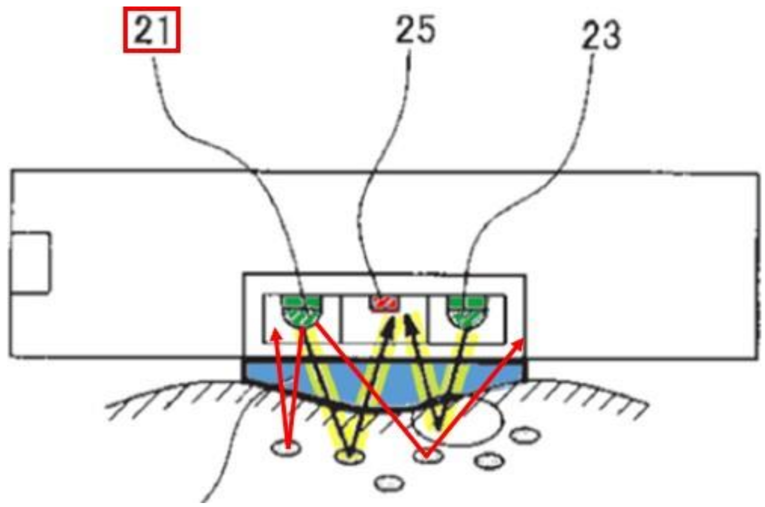
45. In short, based at least on the principle of reversibility, a POSITA would have understood that both configurations of LEDs and detectors—*i.e.*, with the LED at the center as in Aizawa or with the detector at the center as in Inokawa—would identically benefit from the enhanced light-gathering ability of a convex

lens/protrusion.

ii. Masimo ignores the behavior of scattered light in a reflectance-type pulse sensor

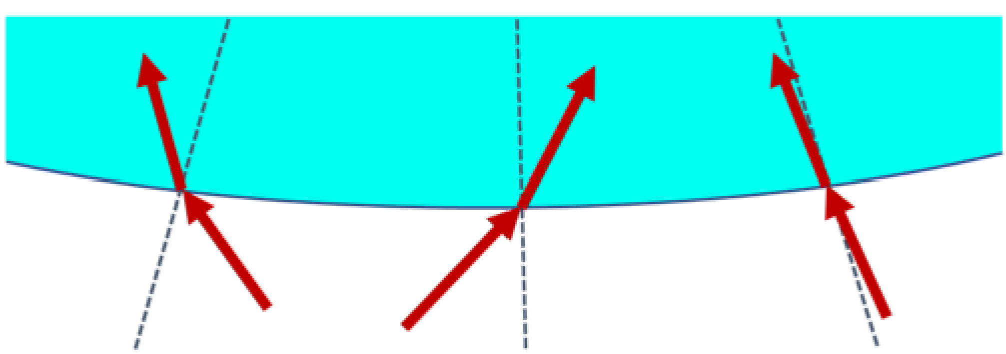
46. Because Aizawa is a reflectance-type pulse sensor that receives diffuse, backscattered light from the measurement site, its cover/lens cannot focus all incoming light toward the sensor's center. Ex. 2006, 163:12-164:2 ("A lens in general…doesn't produce a single focal point"). Indeed, reflectance-type sensors work by detecting light that has been "partially reflected, transmitted, absorbed, and scattered by the skin and other tissues and the blood before it reaches the detector." APPLE-1023, 86. A POSITA would have understood that light which backscatters from the measurement site after diffusing through tissue reaches the active detection area from various random directions and angles. APPLE-1056, 803; APPLE-1023, 90, 52.

47. As noted above, basic law of refraction, namely Snell's law, dictates this behavior of light. APPLE-1061, 84; APPLE-1062, 101; APPLE-1053, 80:20-82:20; APPLE-1023, 52, 86, 90. For example, referring to Masimo's version of Inokawa's FIG. 2, further annotated below to show additional rays of light emitted from LED 21, it is clearly seen how some of the reflected/scattered light from the measurement site does not reach Inokawa's centrally located detector:



APPLE-1008, FIG. 2 (annotated); POR, 14.

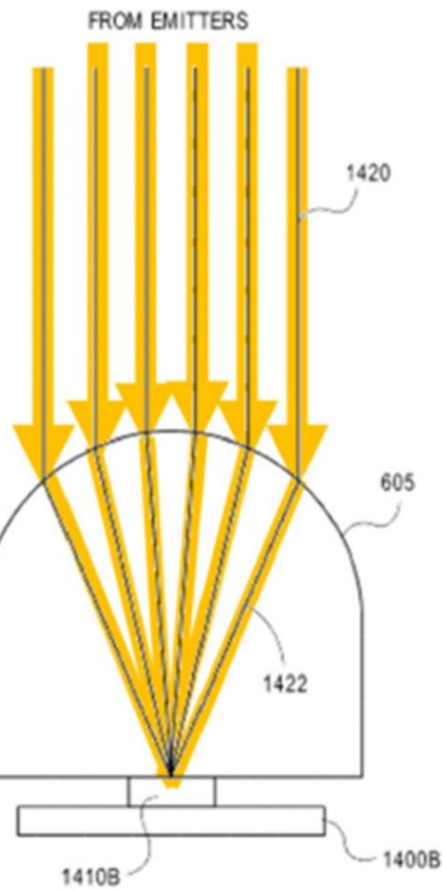
48. For these and countless other rays that are not shown, there is simply no way for a cover to focus all light at the center of the sensor device. APPLE-1061, 84; APPLE-1062, 101; APPLE-1053, 80:20-82:20. The illustration I provide below shows how Snell's law determines a direction of a backscattered ray within a convex cover, thus providing a stark contrast to Masimo's assertions that all such rays must be redirected to or towards the center:



49. Indeed, far from focusing light to the center as Masimo contends, Ohsaki's

convex cover provides a slight refracting effect, such that light rays that may have otherwise missed the detection area are instead directed toward that area as they pass through the interface provided by the cover. This is particularly true in configurations like Aizawa's in which light detectors are arranged symmetrically about a central light source, so as to enable backscattered light to be detected within a circular active detection area surrounding that source. APPLE-1023, 86, 90. The slight refracting effect is a consequence of the similar indices of refraction between human tissue and a typical cover material (e.g., acrylic). APPLE-1057, 1486; APPLE-1058, 1484).

50. To support the misguided notion that a convex cover focuses all incoming light at the center, Masimo relies heavily on the '194 patent's FIG. 14B (reproduced below):



APPLE-1001, FIG. 14B (as annotated at POR, 49)

51. Masimo and Dr. Madisetti treat this figure as an illustration of the behavior of all convex surfaces with respect to all types of light, and conclude that "a convex surface condenses light away from the periphery and towards the sensor's center." POR, 48-49; APPLE-1054 ("…a POSA viewing [FIG. 14B]…would understand that light, ***all light***, light from the measurement site is being focused towards the center").

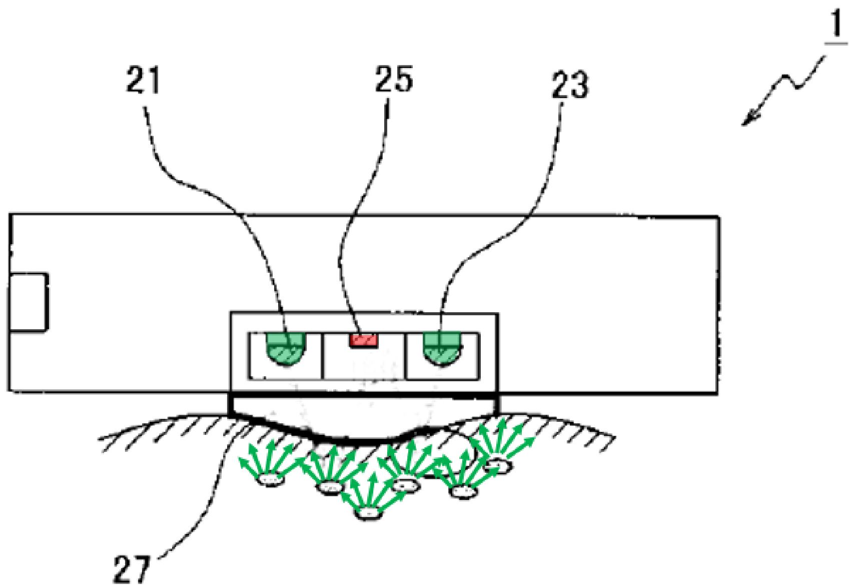
52. But the incoming collimated light shown in FIG. 14B is not an accurate representation of light that has been reflected from a tissue measurement site. The light rays (1420) shown in FIG. 14B are collimated (i.e., travelling paths

parallel to one another), and each light ray's path is perpendicular to the detecting surface.

53. By contrast, the detector(s) of reflectance type pulse detectors detect light that has been "partially reflected, transmitted, absorbed, and scattered by the skin and other tissues and the blood before it reaches the detector." APPLE-1023, 86. For example, a POSITA would have understood from Aizawa's FIG. 1(a) that light that backscatters from the measurement site after diffusing through tissue reaches the circular active detection area provided by Aizawa's detectors from various random directions and angles, as opposed to all light entering from the same direction and at the same angle as shown above in FIG. 14B. APPLE-1023, 52, 86, 90; APPLE-1017, 803-805; *see also* APPLE-1012, FIG. 7. Even for the collimated light shown in FIG. 14B, the focusing of light at the center only occurs if the light beam also happens to be perfectly aligned with the axis of symmetry of the lens. If for example, collimated light were to enter the FIG. 14B lens at any other angle, the light would focus at a different location in the focal plane. Further, if the light were not collimated, so that rays enter the lens with a very wide range of incident angles, there would be no focus at all, and many rays will be deflected away from the center. Moreover, since "the center" takes up a very small portion of the total area under the lens, the majority of rays associated with diffuse light entering the lens would arrive at locations away from the center.

54. The light rays from a diffuse light source, such as the LED-illuminated

tissue near a pulse wave sensor or a pulse oximeter, include a very wide range of angles and directions, and cannot be focused to a single point/area with optical elements such as lenses and more general convex surfaces. The example figure below illustrates light rays backscattered by tissue toward a convex lens; as consequence of this backscattering, a POSITA would have understood that the backscattered light will encounter the interface provided by the convex board/lens at all locations from a wide range of angles. This pattern of incoming light cannot be focused by a convex lens towards any single location.



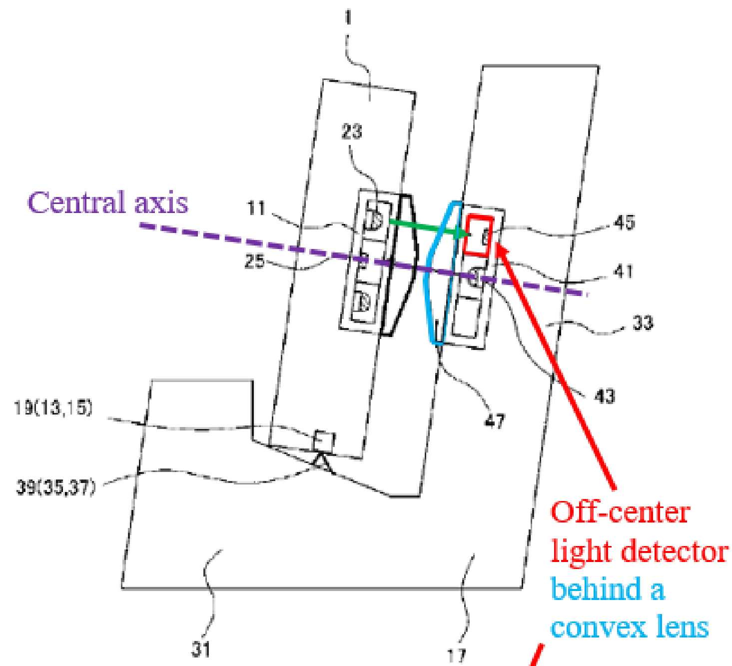
APPLE-1061, 141 (annotated)

55. To the extent Masimo contends that only *some* light is directed "towards the center" and away from Aizawa's detectors in a way that discourages combination, such arguments also fail. Indeed, far from *focusing* light to a single central point, a POSITA would have understood that Ohsaki's cover provides a slight refracting effect, such that light rays that may have missed the active

detection area are instead directed toward that area as they pass through the interface provided by the lens. APPLE-1023, 52; APPLE-1007, [0015]; APPLE-1061, 87-92, 135-141; APPLE-1054, 60:7-61:6, 70:8-18.

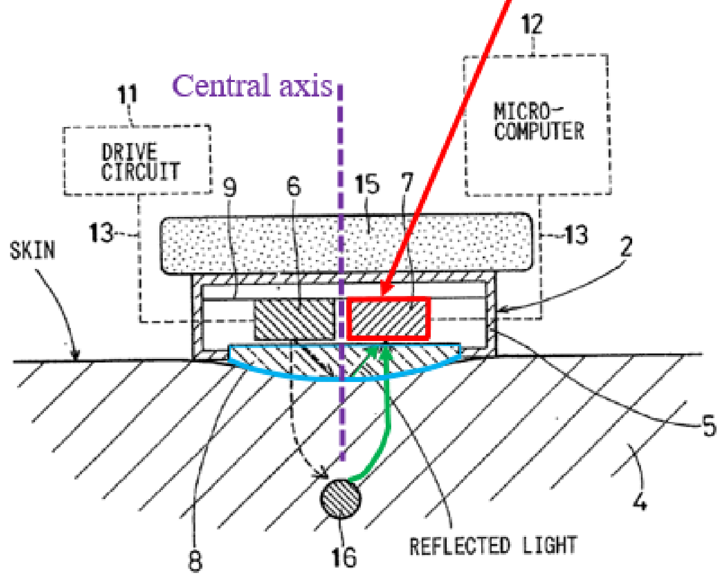
56. Masimo's technically and factually flawed argument is exposed by multiple prior art references, including the Ohsaki and Inokawa references which are the key elements of our combinations. As shown in the figures below, Ohsaki and Inokawa both show embodiments which use a convex lens to direct light to detectors that are not located at the center of a sensor. APPLE-1014, FIG. 2; APPLE-1008, FIG. 3. In Inokawa's Figure 2, an off-center emitter and sensor are configured to send and receive text messages, and are capable of success, even though the detector is not positioned at the center.

(FIG. 3)



APPLE-1008, FIG. 3

FIG. 2

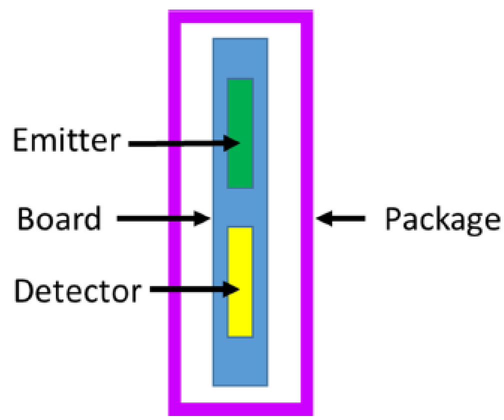


APPLE-1014, FIG. 2

57. If, as asserted by the Patent Owner, a convex lens is required to condense, direct, or focus the light to the center, the embodiments disclosed by Ohsaki and Inokawa would all fail because there is no detector at the center to detect all of

the light that would be directed towards the center by the convex board. The Ohsaki and Inokawa embodiments (reproduced above) do not show or otherwise teach that its convex board directs all light towards the center.

58. Moreover, even in Patent Owner and Dr. Madisetti's illustration (shown below), which represents their understanding of Ohsaki's FIGS. 1 and 2, the detector is not located in the center. Ex. 2004, ¶38. If Patent Owner and Dr. Madisetti's arguments were correct (which they are not), Ohsaki embodiments in FIGS. 1 and 2 would fail to produce a functioning pulse wave sensor—which is not the case—and Patent Owner has never claimed the same either.



Ex. 2004, ¶38

59. For all of these reasons, including details from the interpretation of Ohsaki's embodiment provided by Dr., Madisetti and the Patent Owner, it would have been obvious to a POSITA that a convex cover would have been successfully used with a sensor design with peripheral detectors (as in Aizawa and Ohsaki), and that it would be reasonable to expect the benefits of improved adhesion as explained above and in my previous declaration.

D. A POSITA would have been motivated to select a convex cover to protect the optical elements

60. Masimo contends that "a POSITA would have understood that Aizawa's flat plate would provide better protection than a convex surface" and be "less prone to scratches." POR, 54-55. Even assuming this to be true, one possible disadvantage that competes with the known advantages of applying Ohsaki's teachings to Aizawa's sensor would not have negated a POSITA's motivation to combine. Moreover, a POSITA would have understood the ***multiple*** advantages of a convex cover described in my earlier declaration outweigh any alleged possibility of scratching (which, at any rate, has nothing whatsoever to do with the protection of optical elements within Aizawa's sensor). Moreover, by choosing a suitable material of the protrusion to be scratch-resistant, such as glass, it would have been obvious for a POSITA to achieve both benefits (light gathering and scratch-resistance) at once.

E. Patent Owner mischaracterizes Aizawa's principle of operation

61. Masimo appears to be arguing that Aizawa's photodetectors cannot be connected in parallel because Aizawa seeks to "help address sensor dislocation" and that this function, for some reason, cannot be maintained if its detectors were connected in parallel. POR, 57-59. As I explain in more detail below, this argument from Patent Owner either completely misunderstands and/or mischaracterizes Aizawa's actual teachings.

62. As I mentioned during my deposition, a POSITA would have recognized

and/or found it obvious that the photodetectors of Aizawa are connected in parallel. Ex. 2026, 72:3-9. This is because a POSITA would have known that connecting multiple photodetectors together in parallel allows the current generated by the multiple photodetectors to be added to one another, which would subsequently ensure that even if one of multiple sensors connected in parallel were to be displaced so as to receive no signal, the fact that all the sensors are connected in parallel such that their signals are summed means that a signal will still be detected, in accordance with Aizawa's objective. As explained by Aizawa, the pulse rate is determined by computing the number of outputs above the threshold value per unit time (Aizawa paragraph 28), which is consistent with how a POSITA would consider analyzing the output based on summing of the sensor currents. I explained this previously in my first declaration. APPLE-1003, ¶¶93-94. Thus, to the extent Aizawa itself doesn't expressly teach connecting its photodetectors in parallel, this is merely an implementation detail that a POSITA would have been well aware of (and in fact performed very commonly). *See* APPLE-1024, 3017; APPLE-1025, 4:23-30. Patent Owner seems to be of the view that FIG. 3 of Aizawa somehow supports their false assertion that Aizawa's sensors cannot be connected in parallel; however, FIG. 3 is merely a "schematic diagram" that is provided to illustrate what a waveform looks like. Indeed, there is no disclosure anywhere in Aizawa to suggest that it is even capable of somehow monitoring the signals of each photodetector, and there is certainly no

need to do so if its sensors are connected in parallel. APPLE-1006, [0019], [0028], FIG. 1(b). Instead of attributing the ability to account for sensor displacement to individually connected/monitored photodetectors, as Masimo appears to contend, Aizawa actually explains that the ability to account for sensor displacement comes from, among other things, disposing its photodetectors "around the light emitting diode and not linearly" and by "expand[ing]...the light receiving area." APPLE-1006, [0009], [0012]. Not surprisingly, these are precisely some of the benefits provided by the Aizawa combination as set forth.

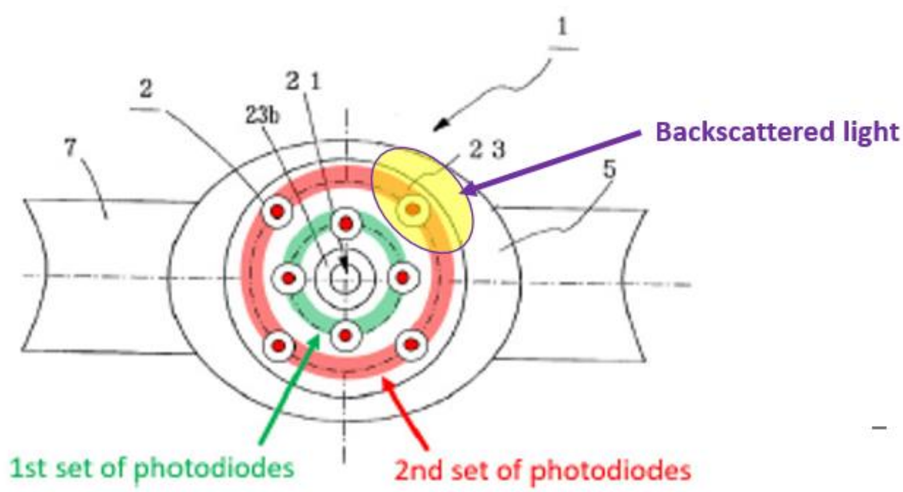
63. Thus, connecting Aizawa's photodetectors in parallel allows Aizawa to account for sensor displacement, instead of preventing it as Masimo alleges, since the signals from all the detectors will be included in the output, thereby allowing the system to account for any one detector that may not be receiving a signal due to displacement.

F. A POSITA would have been motivated to add a second ring of sensors to Aizawa

64. I previously explained at length why a POSITA would have been motivated to add a second ring of sensors to Aizawa, most notably to allow the modified system to "collect a bigger portion of backscattered light intensity." APPLE-1003, ¶¶, 57, 69, 74, 100-101. Yet inexplicably, Masimo argues that "Petitioner gives no plausible reason why a POSITA would have been motivated to modify Aizawa to add an entire second ring of four detectors farther from the emitter...." POR, 60; *see also* POR, 62 ("Petitioner never explains why, given

these straightforward options to increase signal strength, a POSITA would instead add an entire new circle of detectors farther from the emitter....").

65. But as I previously explained, adding a second ring of sensors to Aizawa allows the modified Aizawa system to "widen[] the active area of the PD" and consequently "collect a bigger portion of backscattered light intensity." APPLE-1003, ¶100; APPLE-1024, 3019. To illustrate, as shown below, a measurement scenario where the backscattered light only reaches the area highlighted in yellow would not result in light detection without the presence of additional sensors provided by the second ring:



APPLE-1006, FIG. 1(a)

66. Like I said during my deposition, "having a larger detector area is beneficial" because this would "fill up more of the space, that would give you the opportunity to capture more light reflected back from the tissue." Ex. 2026, 102:5-104:4.

67. Additionally, contrary to Masimo's arguments, adding a second ring of

detectors would not have led to an undesirable increase in power consumption. POR, 59-62. Among other things, the LEDs, not the photodetectors, are responsible for consuming the dominant power in the system. Ex. 2026, 104:5-105:14. Thus, widening the detection area to collect a bigger portion of backscattered light, as would be the case with the modified Aizawa system with two rings of detectors, would result in improved light collection efficiency by allowing additional light to be captured and thereby allowing a lower brightness of LEDs to be used, which would result in reduced power consumption. APPLE-1003, ¶¶68-69.

68. Even assuming for the sake of argument that power consumption is increased through this modification, which for reasons I explained above it would not, a POSITA nevertheless would have been capable of weighing potential tradeoffs, for instance increased power consumption vs. collection of more of the backscattered light than would be possible if detector placement was limited to only one ring. Such design choices are routinely made by a POSITA in consideration of the overall design/engineering objectives.

G. A POSITA would have been motivated to keep the first and second rings of detectors separate

69. Not able to dismiss the clear benefits that Mendelson-2003's two-ring design would provide to Aizawa, Masimo further tries to dismiss such teachings as being for "performing experiments." POR, 62. Masimo argues that "even if a POSITA would have added a second ring of detectors, Mendelson 2003

evidences that a POSITA would not have kept the first and second ring of detectors separate or separately amplified the aggregated signals." POR, 66. They appear to be arguing that Mendelson-2003 requires a single large photodetector that covers the same area covered by the two rings of detectors.

70. But Mendelson-2003 does not say that using a single, large detector is somehow superior to using multiple, smaller detectors. Instead, the main premise behind Mendelson-2003 is that the two situations are equivalent; that is why they are able to use one configuration (*e.g.*, two rings of detectors) in place of the other (*e.g.*, single large detector). Thus, a POSITA, looking to implement the teachings of Mendelson-2003 regarding the benefits of expanding the detection area, would have recognized that one way to achieve the same would be through the precise configuration as taught by Mendelson-2003, namely using two rings of discrete photodetectors that are each connected in parallel and that each provide a separate stream. Indeed, it is well known that a single larger photodetector can be replaced with multiple smaller ones. *See, e.g.*, APPLE-1016, 915 ("[W]e showed that a concentric array of ***either discrete PDs, or an annularly-shaped PD ring***, could be used to increase the amount of backscattered light detected..."). Thus, a POSITA trying to maximize the detection area to increase sensitivity and lower power consumption, as in Mendelson-2003, would have recognized that one way to implement this configuration is to, like Mendelson-2003, use two rings of parallel detectors.

71. Lastly, as I previously described in my first declaration, keeping the two signal streams separate provides multiple other benefits, such as detecting sensor displacement as well as being able to more reliably detect weak signals that are only picked up by the outer ring, for example, by utilizing different gain in the amplification of signals captured by the outer ring. *See* APPLE-1003, ¶¶95-97. Masimo's arguments that the benefits of maintaining separate streams as per Mendelson '799 in order to detect dislocation is inapplicable to the modified Aizawa system is misplaced because a POSITA would have recognized that Mendelson '799's general teachings regarding the comparison of "near" and "far" detectors in order to sense dislocation is more broadly applicable to the "near" and "far" rings in Aizawa-Mendelson-2003. APPLE-1025, 12:62-13:5, 13:19-30; APPLE-1003, ¶95. Moreover, Masimo's arguments that "the weaker signals at the outer ring are precisely why a POSITA would have used Aizawa's existing single ring embodiment" entirely misses the point that expanding the detection area by use of additional rings gives the system an opportunity to pick up weaker signals that otherwise would have been missed completely. POR, 66.

III. Ground 2 Establishes Obviousness

72. Masimo argues that Ground 2 should be rejected for the same reasons as Ground 1. As explained above, Ground 1 establishes obviousness of the claimed features, thus these grounds additionally render the claims obvious.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.

Petitioner,

v.

MASIMO CORPORATION,

Patent Owner.

Case IPR2020-01716
U.S. Patent 10,702,194

DECLARATION OF VIJAY K. MADISETTI, PH.D.

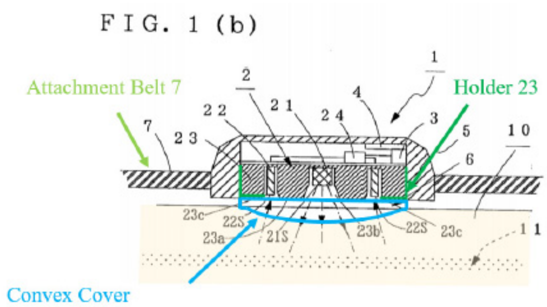
Masimo Ex. 2004
Apple v. Masimo
IPR2020-01716

measurements. Finally, a POSITA would have believed that adding a convex-shaped cover to Aizawa's sensor would have a detrimental optical impact by directing light away from Aizawa's peripherally located detectors, resulting in reduced signal strength and decreased detection efficiency. Further a POSTIA would not have selected a convex shape for protecting Aizawa's sensor components because of the complications and problems associated with adding a convex surface to Aizawa's flat plate.

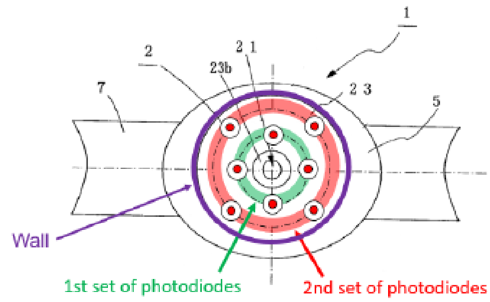
1. A POSITA Would Have Understood That Ohsaki's Rectangular Board Would Not Work With Aizawa's Circular Sensor Arrangement

a) Modifying Ohsaki's Rectangular Board Would Eliminate The Limited Advantage Of Reduced Slipping Taught By Ohsaki

53. Dr. Kenny's combination changes Ohsaki's structure and eliminates the longitudinal shape that gives Ohsaki's rectangular board the ability to fit within the user's anatomy and prevent slipping. Ex. 1003 ¶78; Ex. 1014 ¶[0019]. Dr. Kenny's illustrated combination changes Ohsaki's rectangular board (discussed in Sections VII.A.1-2, above) and makes it circular so that it can cover Aizawa's holder 23 (which Dr. Kenny outlined in purple in the figure below):



Dr. Kenny's illustration of the combination of Ohsaki, Aizawa, Mendelson 2003, and Mendelson 2006 (Ex. 1003 ¶105)

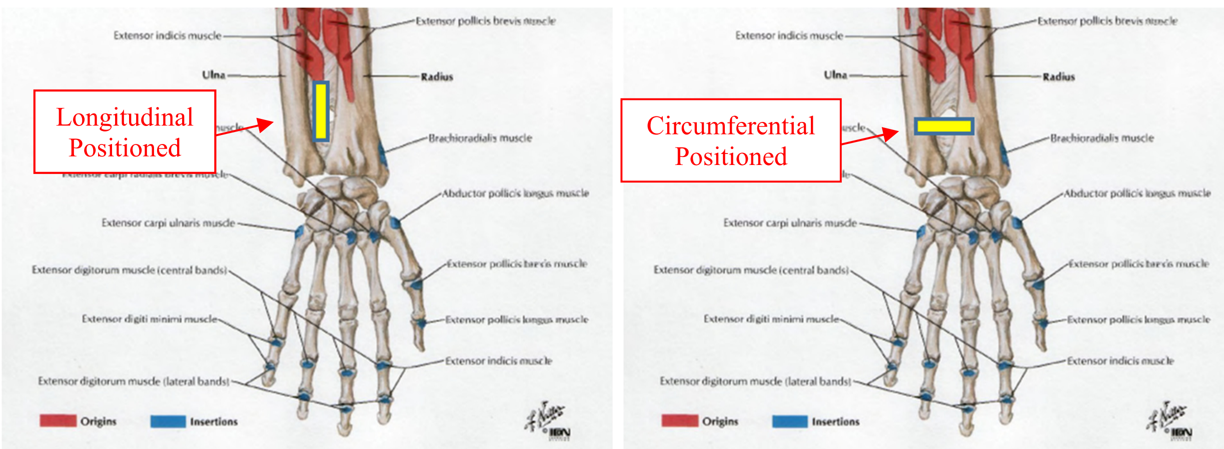


Dr. Kenny's illustration of Aizawa's modified circular sensor (Ex. 1003 ¶104)

54. Dr. Kenny asserts that a POSITA would have been motivated to add Ohsaki's rectangular board to Aizawa's circular sensor to improve adhesion. Ex. 1003 ¶78; *see also, e.g.*, ¶¶75, 105. As an initial point, Ohsaki does not specifically discuss improving adhesion, and instead refers to a particular configuration that prevents slipping and various other configurations that have a tendency to slip. Ex. 1014 ¶¶[0006], [0010], [0019], [0023], [0025]. Dr. Kenny equates Ohaski's disclosure of a convex surface that prevents slippage with "improving adhesion." Ex. 1003 ¶75 (citing Ex. 1014 ¶[0025]). But Dr. Kenny's proposed modification eliminates the longitudinal shape that Ohsaki identifies as an important part of reducing slipping. Ex. 1014 ¶[0019].

55. Ohsaki places its linear, longitudinal sensor on the backhand side of a user's wrist to avoid interacting with bones in the wrist. *See* Ex. 1014 ¶¶[0006] (discussing need to avoid pressing on "two bones (the radius and the ulna)"), [0024] ("the radius and the ulna inside the user's wrist 4 are not pressed"); *see*

also, *e.g.*, ¶¶[0023]-[0024], Abstract, Title, Fig. 1 (Ohsaki device worn on back side of wrist). As illustrated below (left), the forearm bones (the radius and ulna) on the arm's backhand (or watch) side create a longitudinal opening at the junction between the wrist and forearm with no muscle insertions. Ex. 2010 at 49 (Plate 434). The radius and ulna, against which Ohsaki warns against pressing (Ex. 1014 ¶¶[0006], [0024]), are on either side of this longitudinal opening.



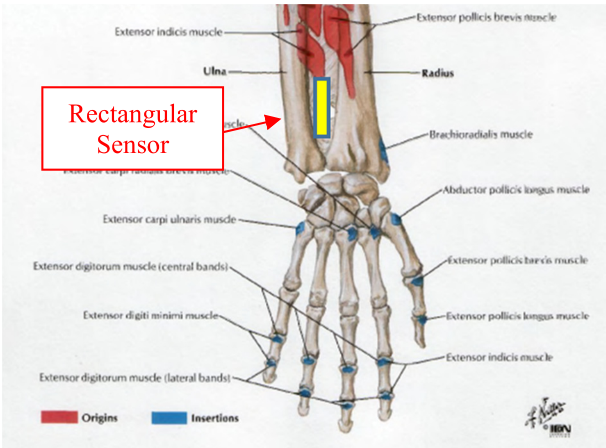
Anatomical drawing of the back side (posterior) of the hand, wrist, and forearm (partial view from Ex. 2010 at 49 (Plate 434))
Left: Conceptual view of how a rectangular sensor that is positioned in longitudinal direction on the wrist/forearm can avoid the radius and ulna
Right: Conceptual view of how the same rectangular sensor placed in the circumferential direction on wrist/forearm interacts with the radius and ulna

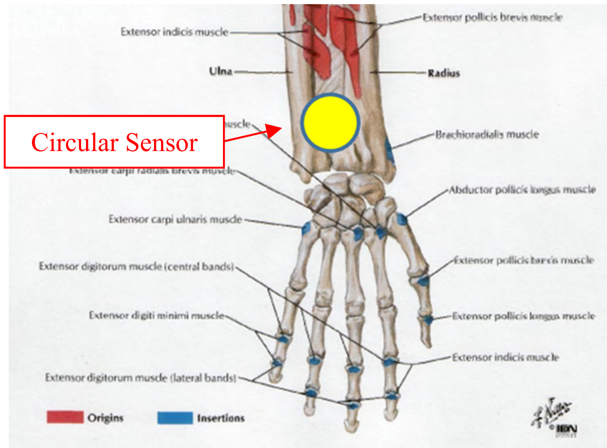
56. Ohsaki indicates that its sensor's longitudinal direction needs to be aligned with the longitudinal direction of the longitudinal opening of the user's arm to prevent slipping. Ex. 1014 ¶[0019]. If the sensor's longitudinal direction is aligned with the circumferential direction of the user's wrist, the undesirable result is "a tendency [for Ohsaki's sensor] to slip off." Ex. 1014 ¶[0019]. As

illustrated above (right), a rectangular structure like Ohsaki's sensor and board that is aligned with the circumferential direction of the user's wrist undesirably interacts with the radius and ulna, which Osaki warns against. Ex. 1014 ¶¶[0006], [0024]. In contrast, a rectangular structure aligned with the longitudinal direction of the user's wrist can avoid pressing against the radius and ulna.

57. Thus, a POSITA would have understood that changing the shape of Ohsaki's rectangular board to circular would not preserve its ability to prevent slipping. Instead, if Ohsaki's rectangular board were changed into a circular shape, a POSITA would have believed it would have resulted in slipping, and thus eliminated the advantage of Ohsaki's board. This is because a circular shape extends equally in all directions, including in the circumferential direction of the user's wrist, which Ohsaki explains results in slipping. Ex. 1014 ¶[0019]. As a result, a circular shape cannot be placed in a longitudinal direction and thus cannot align with the longitudinal direction of the user's wrist, as taught by Ohsaki. As illustrated below, unlike a longitudinal sensor, a symmetrical circular shape (with a diameter equal to the long side of the rectangle, below left) would not fit within the user's anatomy in a way that it could avoid undesirably pressing against the user's radius and ulna, which Ohsaki cautioned against.

<u>Ohsaki's Longitudinal Teachings</u> <u>Dr. Kenny's Proposed Combination</u>





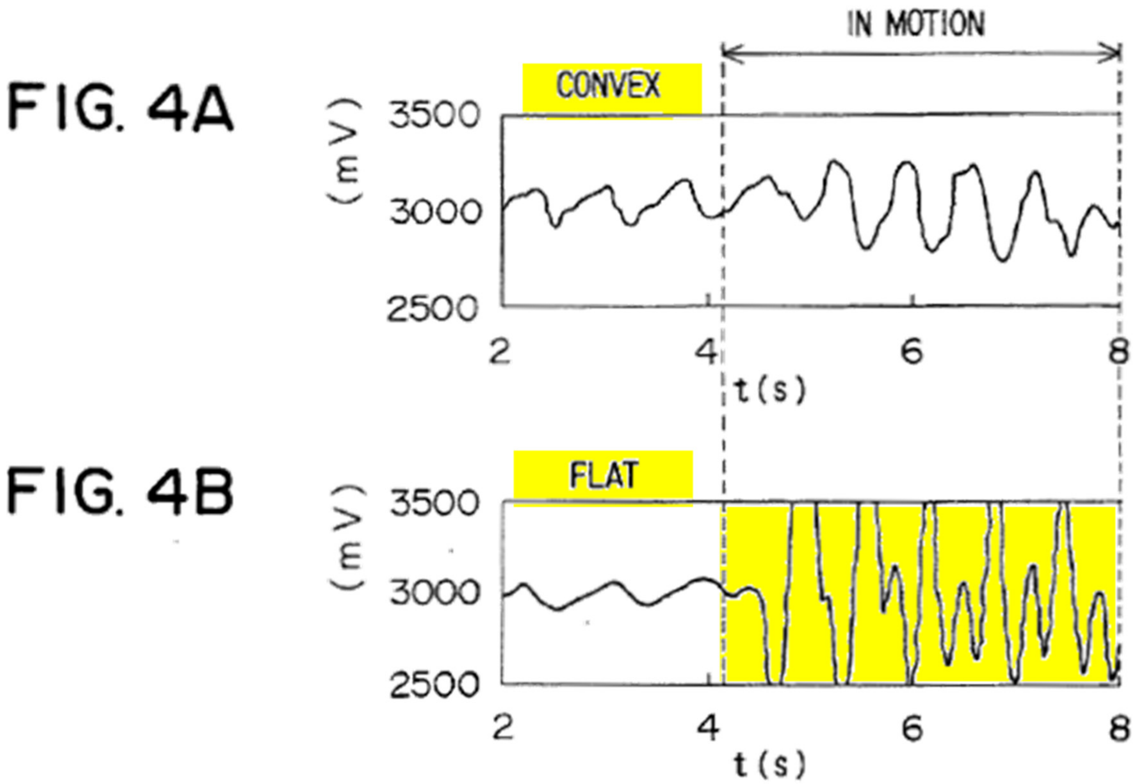
Anatomical drawing of the back side (posterior) of the hand, wrist, and forearm (partial view from Ex. 2010 at 49 (Plate 434))
Left: Conceptual view of how a rectangular sensor that is positioned in longitudinal direction on the wrist/forearm can avoid the radius and ulna
Right: Conceptual view of how a circular sensor with the same diameter as the length of the rectangular board interacts with the radius and ulna

58. Because a symmetrical circular shape will press on the user's arm in all directions, it will interact with the user's bone structure. Ohsaki teaches that such interactions with the user's anatomy are undesirable and result in slipping. Ex. 1014 ¶¶[0006], [0023]-[0024].

59. Dr. Kenny did not discuss Ohsaki's disclosure that when Ohsaki's rectangular sensor was placed in one orientation (up-and-down the arm), it helped prevent slipping. Ex. 1014 ¶[0019]. Dr. Kenny also did not discuss Ohsaki's explanation that rotating the sensor 90 degrees, such that the long direction points in the circumferential direction of the user's wrist, the sensor "has a tendency to slip." Ex. 1014 ¶[0019]; *see* Ex. 1003 ¶¶59-60, 75-83.

identified by Ohsaki corresponds to the irregular pattern shown in Figure 3B, compared to the pattern of measurements from the back side of the wrist shown in Figure 3A. For measurements using a convex board on the back side of the wrist, Ohsaki explains Figure 3A shows "the pulse wave is detected stably without being affected by the movement of the user's wrist...." Ex. 1014 ¶[0024].

79. Dr. Kenny does not cite or discuss Ohsaki's Figures 3A-3B when discussing the motivation for modifying Aizawa's palm-side sensor with a lens/protrusion similar to Ohsaki's board. Ex. 1003 ¶¶75-83; *see also* ¶¶103-105. Instead, Dr. Kenny discusses Ohsaki's Figures 4A-4B, which compares measurements using a sensor with a convex surface or a flat surface on the back (i.e., watch) side of the wrist. Ex. 1003 ¶¶76-77.



Ohsaki Figs. 4A-4B comparing convex and flat surfaces
for measurements taken from the back side of the wrist (color added)

80. Ohsaki states that Figure 4B shows that when measurements taken from the back side of the wrist using a sensor with a *flat* surface, "the detected pulse wave is adversely affected by the movement of the user's wrist." Ex. 1014 ¶[0025]. Ohsaki also indicates that a board with a *convex* surface prevents "slip[ping] off the detecting position" on the back side of the wrist, as shown in Figure 4A. Ex. 1014 ¶[0025]; *see also* ¶¶[0023]-[0024] (comparing tendency to slip on front and back side of wrist). Figure 4A, which illustrates Ohsaki's convex sensor placed on the back side of the wrist, contrasts with the measurements shown in Figure 3B (which illustrates a convex surface slips on the palm side of

the wrist). Figure 4A is consistent with Figure 3A (which illustrates a convex surface has comparatively less motion signal on the back side of the wrist). Taken together, A POSITA would have understood that Ohsaki's convex surface may prevent slipping on the back side of the wrist, if it is positioned appropriately (e.g., in the correct orientation with the long side up-and-down the wrist). Ex. 1014 ¶¶[0019], [0023]-[0025], Figs. 3A-3B, 4A-4B.

81. The rest of Ohsaki's disclosure recognizes the limitations on any benefit derived from its convex surface. Ohsaki repeatedly specifies that its sensor "is worn on the back side of a user's wrist corresponding to the back of the user's hand." Ex. 1014 Abstract; *see also* Title ("Wristwatch-Type Human Pulse Wave Sensor Attached On Back Side Of User's Wrist"), ¶[0008] (The "sensor according to the present invention…is worn on the back side of the user's wrist corresponding to the back of the user's hand."), ¶[0009] ("attached on the back side of the user's wrist by a dedicated belt"), ¶[0016] ("worn on the back side of the user's wrist"), ¶[0024] ("[T]he detecting element 2 is stably fixed to the detecting position of the user's wrist" when arranged on the back side of the user's wrist 4.). The only other possible location mentioned for placement of Ohsaki's sensor is "the back side of the user's forearm," which is adjacent to the wrist. Ex. 1014 ¶¶[0016], [0030]. Thus, in my opinion, for these reasons a POSITA would

not have been motivated to use Ohsaki's longitudinal board, which is designed to be worn on the back of a user's wrist, with Aizawa's palm-side sensor.

c) **A POSITA Would Not Have Been Motivated To Eliminate The Identified Benefits Of Aizawa's Flat Adhesive Acrylic Plate By Including A Lens/Protrusion Similar To Ohsaki's Board**

82. Dr. Kenny asserts that a POSITA would have been motivated to modify Aizawa's flat adhesive acrylic plate "to include a lens/protrusion (right), similar to Ohsaki's translucent board 8, so as to improve adhesion between the user's wrist and the sensor's surface, improve detection efficiency, and protect the elements within the sensor housing." Ex. 1003 ¶78. But a POSITA motivated to improve Aizawa's palm-side sensor would not have been motivated to add Ohsaki's convex board. As discussed above, Ohsaki teaches a POSITA that its convex board only provides advantages on the back side of the wrist, in a particular orientation. Ex. 1014 ¶¶[0019], [0025]. Ohsaki further teaches that on the palm side (front side) of the wrist, a sensor with a convex board, "has a tendency to slip off the detecting position of the user's wrist." Ex. 1014 ¶[0023], Figs. 3A-3B.

83. As discussed above, Aizawa teaches that a flat acrylic plate improves adhesion between the sensor and skin on the palm side of the wrist. *See* Sections VII.A.3, VII.B.2.a, above. Taken individually and together, both Ohsaki and Aizawa undermine Dr. Kenny's proposed addition of a convex lens/protrusion

similar to Ohsaki's translucent board to Aizawa's palm-side sensor to improve adhesion. Ex. 1003 ¶78; *see also, e.g.* ¶¶105-108. This is because, as explained above (Sections VII.B.2.a-b): (1) Aizawa teaches a *flat* acrylic plate *improves* adhesion on the wrist's *palm* side; (2) Ohsaki teaches a *convex* board "has a tendency to *slip*" on the wrist's *palm* side. As a result a POSITA reading Aizawa and Ohsaki would have affirmatively avoided modifying Aizawa's flat acrylic plate—which is taught to improve adhesion at Aizawa's sensor location on the palm side of the wrist—with a convex lens/protrusion similar to Ohsaki's convex board because Ohsaki's convex board is taught to slip on the palm side of the wrist where Aizawa's sensor is positioned. The table below summarizes these teachings.

	Front (Palm) Side	**Back Side**
Flat	Flat acrylic plate improves adhesion Ex. 1006 (Aizawa) ¶[0013]; *see also* ¶¶[0026], [0030], [0034], Fig. 1B **(Aizawa's sensor)**	Tends to slip Ex. 1014 (Ohsaki) ¶[0025], Figs. 4A-4B
Convex	Tends to slip Ex. 1014 (Ohsaki) ¶[0023], Figs. 3A-3B	Rectangular convex board prevents slipping Ex. 1014 (Ohsaki) ¶¶[0024]-[0025], Figs. 4A-4B **(Ohsaki's sensor)**

84. Dr. Kenny only considers Ohsaki's discussion of the impact of a convex versus flat surface on the back side of the wrist. *See, e.g.,* Ex. 1003 ¶¶75-

side of the wrist (e.g., longitudinal directionality in the same direction as the arm, a convex surface).

85. Based on Aizawa's teaching that a flat acrylic plate improves adhesion on the palm side of the wrist, and Ohsaki's teaching that a convex surface tends to slip on the palm side of the wrist, a POSITA would have come to the opposite conclusion from Dr. Kenny: that modifying Aizawa's "flat cover…to include a lens/protrusion…similar to Ohsaki's translucent board 8" would _not_ "improve adhesion." *See, e.g.*, Ex. 1003 ¶78. As discussed above in this section, as well as Section VII.B.2, above, generally, Aizawa and Ohsaki, individually and together rebut Dr. Kenny's assertion that incorporating Ohsaki's convex surface is simply improving Aizawa's transparent plate 6 that has a flat surface "to improve adhesion between the user's wrist and the sensor's surface." Ex. 1003 ¶78. Thus, in my opinion, a POSITA would not have been motivated to modify Aizawa's flat acrylic plate, which improves adhesion at the measurement site on the palm side of the wrist, to include a convex lens/protrusion similar to Ohsaki's board, which tends to slip at the measurement site on the palm side of the wrist.

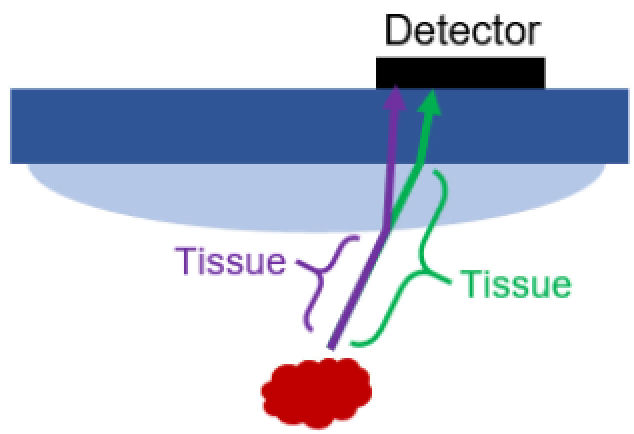
3. A POSITA Would Not Have Been Motivated To Reduce The Measured Optical Signal By Adding A Convex Lens/Protrusion To Aizawa's Sensor

86. Dr. Kenny's proposed combination is also problematic because Dr. Kenny detrimentally modifies Aizawa's flat cover to include a convex

"lens/protrusion" positioned over peripheral detectors surrounding a centrally located emitter. Ex. 1003 ¶¶78, 105-108. As discussed below, a POSITA would have understood that a convex "lens/protrusion" would direct light away from the detectors and thus result in decreased light collection and optical signal strength at the peripheral detectors — not increased signal strength as Dr. Kenny asserts. *See* Ex. 1003 ¶76 (arguing that the convex surface of the translucent board of Ohsaki "increases the strength of the signals").

a) <u>A POSITA Would Have Understood That A Convex Cover Directs Light To The Center Of The Sensor</u>

87. Petitioner and Dr. Kenny both admit that a convex cover condenses light passing through it towards the center of the sensor and away from the periphery. Petitioner and Dr. Kenny both illustrated this phenomenon in a petition filed against a related patent. In the Petition in IPR2020-01520 (Ex. 2019), Petitioner explained that a convex cover redirects light coming into the convex surface towards the center, as shown in Petitioner's figure below:



Petitioner's illustration from a related IPR showing that light hitting a convex surface is directed more centrally than light hitting a flat surface (Ex. 2019 at 45)

88. In his declaration in IPR2020-01520 (Ex. 2020), Dr. Kenny likewise confirmed that when using a convex surface, "the incoming light is 'condensed' toward the center." *See, e.g.,* Ex. 2020 at 69-70 (¶119); *see generally* Ex. 2020 69-71 (¶¶118-120), 115-117 (¶¶199-201). Dr. Kenny included the same illustration as Petitioner, which shows light passing through a convex surface is directed more towards the center, as compared to a flat surface. *See, e.g.*, Ex. 2020 at 69-71 (¶118-120).

89. The '194 Patent also confirms these admissions that a convex surface condenses light away from the periphery and towards the sensor's center. Figure 14B (below) "illustrates how light from emitters (not shown) can be focused by the protrusion 605 onto detectors." Ex. 1001 36:18-21. "When the light rays 1420 enter the protrusion 605, the protrusion 605 acts as a lens to refract the rays into rays 1422." Ex. 1001 36:28-30. As shown by Figure 14B of the '194 Patent,

the convex shape directs light from the periphery toward the center. Ex. 1001 Fig. 14B.

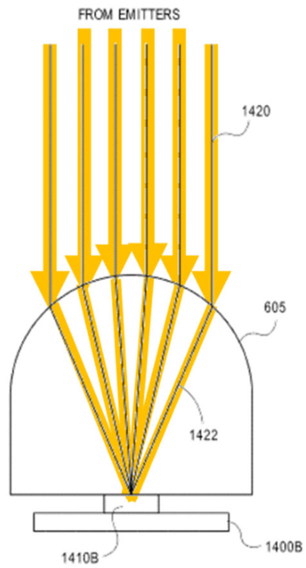
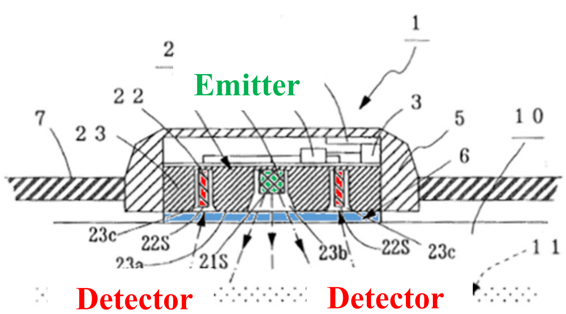


Illustration from the '194 Patent at issue, showing that light hitting a convex surface is directed towards the center
'194 Patent (Ex. 1001) Fig. 14B (highlighting added to show direction of light)

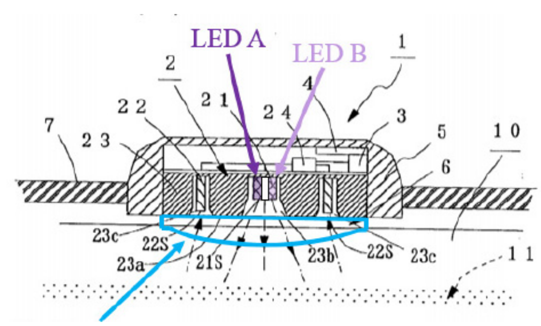
90. Accordingly, Petitioner, Dr. Kenny, and the '194 Patent all support that a POSITA would have understood that a convex lens/protrusion would direct incoming light towards the center of the sensor, as compared to a flat surface. In my opinion, a POSITA would have believed that light passing through a convex surface would have been directed to a more central location as compared to light passing through a flat surface. This would have been viewed as a detrimental result because, as discussed in the next section below, Aizawa's detectors are at the periphery of the sensor.

b) <u>A POSITA Would Not Have Been Motivated To Direct Light Away From Aizawa's Detectors</u>

91. Dr. Kenny asserts that a POSITA would have been motivated to modify Aizawa's flat adhesive acrylic plate with "a lens/protrusion" for improved detection efficiency. Ex. 1003 ¶78. As illustrated below, Aizawa has peripherally located detectors (in red, below left) and a centrally located emitter (in green, below left) under a flat acrylic adhesive plate (in blue, below left). Ex. 1006 Fig. 1B; *see also, e.g.*, ¶¶[0009], [0026]-[0027], [0033], [0036]. Dr. Kenny's combination introduces a convex "lens/protrusion" (in blue, below right) over Aizawa's peripherally located detectors and centrally located light source (*see, e.g.*, Ex. 1003 ¶78):



Aizawa Fig. 1B (cross-section)
Red: detectors; Green: emitter,
Blue: flat plate

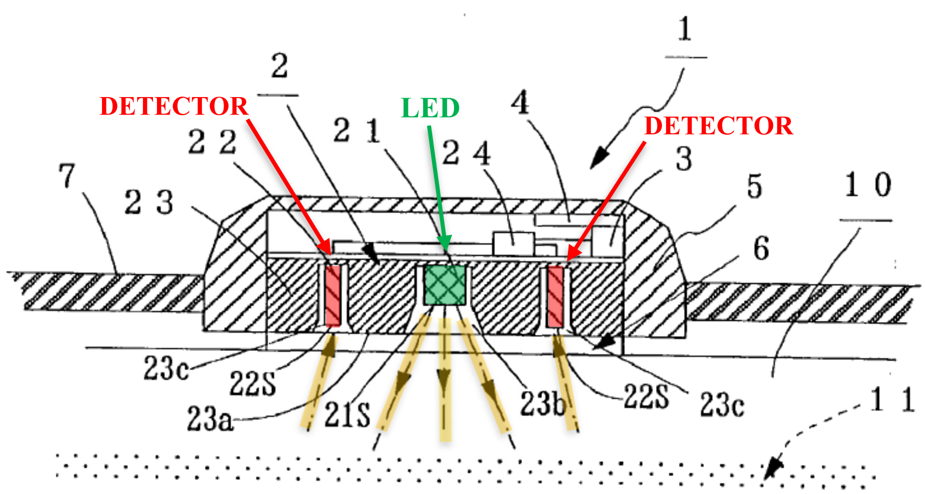


Dr. Kenny's proposed modifications
(Ex. 1003 ¶78)

Aizawa (Ex. 1006 Fig. 2) (color added) (left) versus
Dr. Kenny's proposed combination (Ex. 1003 ¶78) (right)

92. Dr. Kenny asserts that Ohsaki's board "increases the strength of the signals obtainable by Ohsaki's sensor." Ex. 1003 ¶76. However, as discussed

above (Section VII.B.3.a), a POSITA would have believed that adding a convex lens/protrusion to Aizawa's flat adhesive acrylic plate would direct light away from the combination's detectors that are located on the periphery. Aizawa illustrates that the light reaching Aizawa's detectors must travel from the center emitter to the outer periphery of the detectors. Ex. 1006 Fig. 1B, ¶[0027]. Aizawa shows the light path as leaving a single centrally located emitter, passing through the body, and reflecting back to periphery-located detectors (light must travel from the center emitter to the outer periphery to the detectors. Ex. 1006 Fig. 1B, ¶[0027]):



Aizawa Fig. 1B (cross-sectional view, color added)

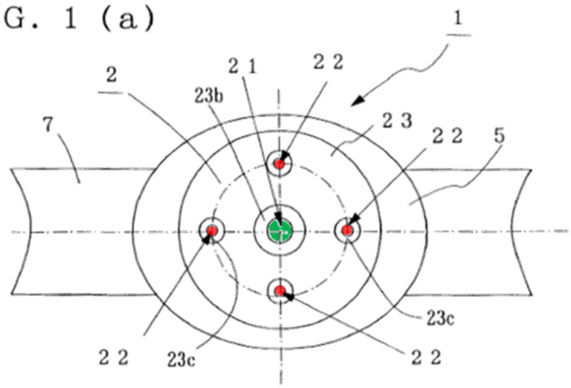
93. Because of the configuration of Aizawa's sensor, with its central emitter and peripheral detectors, and the illustrated light path that requires light from the central emitter to reach the peripheral detectors, a POSITA would have understood that a change directing light to a more central location would decrease

the optical signal at Aizawa's peripheral detectors. Ex. 1006 ¶¶[0026], [0030] (discussing benefits of Aizawa's flat "plate"). Because a POSITA would have believed that adding a convex lens/protrusion would have redirected light to a more central location as compared to Aizawa's flat adhesive acrylic plate, a POSITA would have concluded that Dr. Kenny's proposed modification would decrease light-collection efficiency at Aizawa's peripheral detectors. Thus, I disagree with Dr. Kenny that a POSITA would have been motivated to modify Aizawa's flat plate to add a lens/protrusion similar to Ohsaki's translucent board based on the belief that it would have improved detection efficiency or otherwise increased signal strength. Ex. 1003 ¶78. As discussed above (Section VII.B.3.a) Dr. Kenny, the Petitioner, and the '194 Patent all support that a POSITA would have believed that adding a convex lens/protrusion would result in the light gathered and refracted to a more central location, and thus away from Aizawa's peripheral detectors, as compared to Aizawa's existing flat plate.

94. In addition, the addition of a convex lens/protrusion similar to Ohsaki's is particularly problematic because both Aizawa and Dr. Kenny's illustration of his combination include small detectors with small openings surrounded by a large amount of opaque material. Ex. 1006 Figs. 1A, 1B, 2; *see, also, e.g.*, Ex. 1003 ¶¶78, 89, 98, 99, 104, 134, 139, 144 (Dr. Kenny's

illustrations). Aizawa's top-down view confirms the detectors' small size. Ex. 1006 Fig. 1A.

FIG. 1 (a)



Aizawa's Features

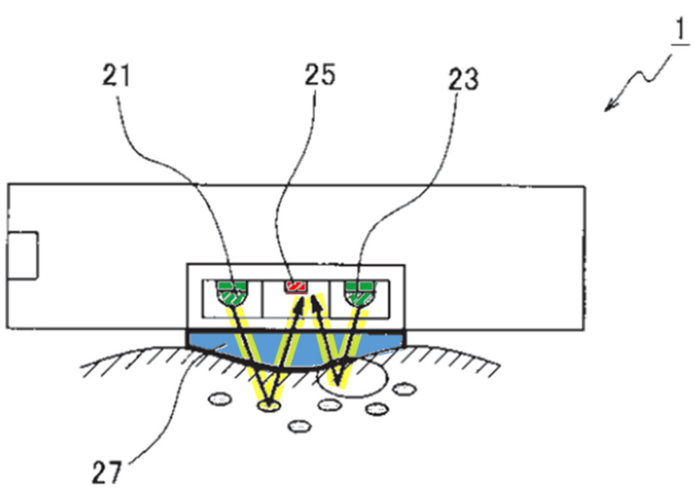
- **Green**: central emitter (21)
- **Red**: peripheral detectors (22)

Aizawa's sensor, showing small detectors (Ex. 1006 Fig. 1A, color added)

95. Thus, Dr. Kenny provides no evidence that a POSITA would have expected a convex lens/protrusion similar to Ohsaki's board to improve detection efficiency at Aizawa's peripheral detectors and increase signal strength. Ex. 1003 ¶¶76, 78. Instead, as explained above (Section VII.B.3.a), a POSITA would have expected that changing Aizawa's flat acrylic plate to a convex lens/protrusion similar to Ohsaki's board would reduce the amount of light gathered and refracted to Aizawa's peripheral detectors. The optical changes resulting from modifying Aizawa's flat surface to include a convex lens/protrusion similar to Ohsaki's board are thus another reason why a POSITA would not have been motivated to make that change.

96. Finally, Dr. Kenny relies on Inokawa for motivation to modify Aizawa's flat surface. Ex. 1003 ¶¶80-83. Dr. Kenny states that Inokawa would

provide a "further rationale" (Ex. 1003 ¶80) to add the proposed a "lens/protrusion" (Ex. 1003 ¶78) to Aizawa. Dr. Kenny states that Inokawa demonstrates "the additional benefit of increasing light collection efficiency, which would in turn lead to an improved signal-to-noise and more reliable pulse detection," based on "refracting/concentrating incoming light signals reflected by the blood." Ex. 1003 ¶81. Unlike Aizawa's circular ring of detectors around a central emitter, Inokawa's sensor is a linear sensor that uses a convex lens (27) to focus light from LEDs (21, 23) positioned on the periphery of the sensor to a single detector (25) in the center. Ex. 1008 ¶[0058], Fig. 2; *see also id.* ¶[0015] ("This lens makes it possible to increase the light-gathering ability of the LED as well as to protect the LED or PD.").



Inokawa's Features

- **Green**: peripheral emitters (21, 23)
- **Red**: central detector (25)
- **Blue**: convex lens (27)
- Arrows showing the direction of light in original, highlighting in yellow added

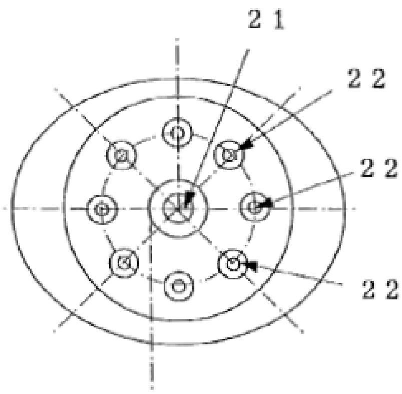
Inokawa Fig. 2 (color added)

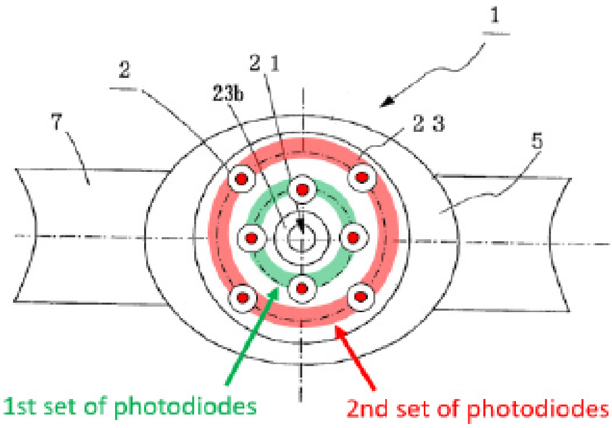
97. As illustrated above, Inokawa's linear detector-emitter configuration is different from than Aizawa's circular detector arrangement. In Inokawa's

sensor, light from Inokawa's periphery-located LEDs will reflect off the body and pass through the lens, which directs incoming light to the centrally located detector. Ex. 1008 ¶[0058]. Inokawa's convex surface thus concentrates incoming light towards the sensor's center, where the detector is located, and away from the periphery. In contrast, Aizawa's detectors are not located at the center—they surround the central emitter. Inokawa would thus have further demonstrated to a POSITA that the proposed combination would decrease light gathering at Aizawa's peripheral detectors, which is the opposite of Dr. Kenny's motivation to combine. Ex. 1003 ¶81.

4. **<u>A POSITA Would Not Have Selected A Convex Cover To Protect The Sensor's Optical Elements</u>**

98. Dr. Kenny also asserts that a POSITA would have been motivated "to modify the [Aizawa] sensor's flat cover…to include a lens/protrusion…similar to Ohsaki's translucent board 8, so as to…protect the elements within the sensor housing." Ex. 1003 ¶78; *see also* ¶105. As illustrated below, Aizawa already includes a flat adhesive acrylic plate (blue) that protects the elements (emitter, detectors) within the PMD housing. Ex. 1006 Fig. 1B; *see also, e.g.*, ¶¶[0023]-[0026], [0030]. Thus, in my opinion, a POSITA would not have been motivated to modify Aizawa's existing flat adhesive acrylic plate to add a convex lens/protrusion similar to Ohsaki's board for protection because a POSITA would have understood that Aizawa's flat cover already protects the sensor's





Aizawa Fig. 4A Dr. Kenny's Proposed Combination (Ex. 1003 ¶72)

108. Dr. Kenny does not give a plausible reason why a POSITA would have been motivated to modify Aizawa's structure and add a second ring of four detectors that is farther from the emitter. Dr. Kenny's suggestion is contrary to Aizawa's illustrated embodiment, which demonstrates that eight detectors readily fit into the existing ring, and assumes add a second ring of four detectors that is farther from the emitter would have some benefit. Ex. 1003 ¶¶71-73. But Mendelson 2003 adds a second ring of detectors farther away from the emitter because there is no room for more detectors in the existing ring. Ex. 1024 Fig. 1. The proposed new "outer" ring of detectors is not needed in Aizawa, and a POSITA would have understood that Dr. Kenny's new outer ring would have received substantially lower light intensity and required relatively greater power consumption to use than additional detectors added to the "inner" ring. *See* Ex. 1024 at 4 (stating optical signal "is inversely related to the separation distance between the PD and the LEDs" and outer ring detectors require LEDs

"significantly higher currents"). A POSITA would have believed the proposed modification would result in greater power consumption as compared to Aizawa's existing 8-detector structure, all placed on the inner ring closer to the detector. This is particularly true because Dr. Kenny also proposes adding a convex cover that would direct light away from the outer ring of periphery-located detectors. *See* Sections VII.B.1-3, above. A POSITA motivated to achieve improved power savings—Dr. Kenny's stated motivation for his modification (Ex. 1003 ¶70)—would not have added an outer ring of detectors to Aizawa, and instead would have added detectors to Aizawa's existing ring as disclosed in Aizawa's already disclosed 8-detector embodiment that positions all eight detectors in a single concentric circle.

109. Dr. Kenny's proposed modification thus changes Aizawa's structure in a way that Mendelson 2003 itself indicates would result in relatively worse power consumption (Ex. 1024 at 4) compared to Aizawa's existing configuration. In my opinion, a POSITA seeking to increase the number of detectors would have implemented Aizawa's existing eight detector arrangement, and not come up with an entirely new configuration with multiple rings of detectors.

detector signals—not detectors connected in parallel as in Mendelson 2003 and in Dr. Kenny's proposed combination. In my opinion, Mendelson '799 would have dissuaded a POSITA from using Mendelson 2003's parallel-connected detector configuration because it would eliminate Mendelson '799's cited benefit, which is derived from individual photodiode signals, by eliminating the ability to extract individual photodiode signals and analyze them individually.

115. Dr. Kenny also indicates that the proposed combination's second ring introduces signal processing problems requiring even more redesign for Aizawa's sensor. Ex. 1003 ¶¶95-97. Dr. Kenny offers the opinion that a POSITA would have "found it obvious, in some implementations, to keep each ring separately wired and connected to its own amplifier." Ex. 1003 ¶97. Dr. Kenny suggests this further modification of an additional amplifier because "the inner ring is likely to produce far greater currents compared to the outer ring due to the above-noted exponential relationship between detected light intensity and distance from the LED." Ex. 1003 ¶97. Dr. Kenny indicates this creates problems because the resulting different magnitude signals are not comparable without additional processing. Ex. 1003 ¶97. Without these further modifications, Dr. Kenny states, "signals detected by the near/first sets of detectors may drown out the weaker signals coming from the far/second sets of detectors, thereby diminishing the enhanced sensitivity and collection efficiency achieved through the widened

detection area." Ex. 1003 ¶97. As discussed above (Section VII.C.2), however, the weaker signals at the outer ring are why a POSITA would have used Aizawa's existing single ring embodiment with eight detectors and not a new, worse performing two ring combination.

116. Even if a POSITA did add a second ring of detectors, Mendelson 2003 itself undermines the notion that a POSITA would have kept the first and second ring of detectors separate and then made an additional modification to separately amplify the aggregated signals. Instead, Mendelson 2003 explains it "combin[ed] both PD sets to simulate ***a single*** large PD area" and notes "battery longevity could be extended considerably by employing ***a*** wide annular PD." Ex. 1024 at 4.

117. Thus, in my opinion, a POSITA would not have modified Aizawa based on Mendelson 2003 in the way proposed by Dr. Kenny.

D. Mendelson 2006 Further Undermines The Proposed Combination

118. Dr. Kenny's combination also includes a fourth reference, Mendelson 2006. Ex. 1003 ¶¶84-86. Dr. Kenny focuses on Mendelson 2006's disclosure related to data transmission and user interface. Ex. 1003 ¶¶84-86. But Mendelson 2006 also teaches a sensor with a single signal stream from a single wide annular photodetector, and confirms this approach extends battery longevity, which is also what Mendelson 2003 states in its conclusion. Ex. 1016 at 1 (Abstract), 4

(conclusion); Ex. 1024 at 4 ("[E]xperiments revealed that battery longevity could be extended considerably by employing ***a wide annular PD*** and limiting SpO_2 measurement to the forehead region" by "employing a wide annular PD"). Mendelson 2006 thus confirms that a POSITA motivated by power consumption would have used "***an*** annular photodetector [i.e., a single photodetector] to reduce power consumption," which would result in a single signal stream Ex. 1016 at 1 (Abstract), 4 (conclusion), Fig. 2 (block diagram with one photodiode). Mendelson 2006 and Mendelson 2003 each demonstrate that a POSITA would have used a single signal stream, and not a first set of at least four photodiodes connected in parallel to provide a first signal stream and a second set of at least four photodiodes connected in parallel to provide a second signal stream, as claimed.

E. The Challenged Dependent Claims Are Nonobvious Over Ground 1

119. As discussed above, in my opinion claim 1 would not have been obvious over the cited references of Ground 1. In addition, in my opinion, the dependent claims would be nonobvious for at least the same reasons. *See* Sections VII.A-D, above.

120. In addition, for the reasons discussed below, dependent claims 13, 17, and 29 are non-obvious for additional reasons. Claim 13 depends from claim 1 and includes the additional limitation: "wherein the protruding convex surface

protrudes a height between 1 millimeter and 3 millimeters." Claim 17 depends from claim 1 and adds the limitation: "wherein the protruding convex surface protrudes a height greater than 2 millimeters and less than 3 millimeters." Claim 29 depends from claim 20 and includes the same additional limitation as claim 17. The '194 Patent provides that particular exemplary convex shapes improve signal strength. Ex. 1001 20:25-34. The '194 Patent discloses: "For example, in one embodiment, a convex bump of about 1 mm to about 3 mm in height and about 10 mm^2 to about 60 mm^2 was found to help signal strength by about an order of magnitude versus other shapes." Ex. 1001 20:29-33. Thus, the '194 Patent explains that an appropriately sized protrusion can dramatically increase the accuracy of the measurements. Ex. 1001 20:25-34.

121. Dr. Kenny identifies no corresponding teaching in Ohsaki, Aizawa, Mendelson 2003, or Mendelson 2006. Ex. 1003 ¶¶147-149, 153, 181. Instead, Dr. Kenny states when "incorporating Ohsaki's teachings, a POSITA would have found it obvious that a device designed to fit on a user's wrist would be on the order of millimeters," and "there would have been a finite range of possible protruding heights, and it would have been obvious to select a protruding height that would have been comfortable to the user." Ex. 1003 ¶¶148-149. But nothing in the grounds references discloses a protrusion with a height either between 1

millimeter and 3 millimeters or greater than 2 millimeters and less than 3 millimeters would have been beneficial, as the inventors discovered.

122. Dr. Kenny suggests two references, Mendelson 2006 and Mendelson 1988 (Ex. 1015), include disclosures of sensor sizes. Ex. 1003 ¶148. But neither Mendelson 2006 nor Mendelson 1988 disclose a cover, let alone a cover with a protrusion. Ex. 1016 Fig. 1 (no view of cover); Ex. 1015 Fig. 2B (showing flat layer of epoxy encapsulating optical components). The flat surface of encapsulating epoxy used with Mendelson 1988's sensor would not have informed or motivated a POSITA to include a cover, much less a cover with a convex protrusion of a particular height.

123. Dr. Kenny seems to select Mendelson 2006 and Mendelson 1988 because they discuss similarly sized sensors (22 mm diameter and 19x19 mm square), which Dr. Kenny argues would also be used with a wrist-worn device. Ex. 1003 ¶148. But both Mendelson 2006 and Mendelson 1988 are forehead sensors, not wrist sensors. Ex. 1016 Abstract ("wireless wearable pulse oximeter developed based on a small forehead mounted sensor"); Ex. 1015 at 1 ("SpO_2 obtained from the forehead"). Dr. Kenny provides no basis to select one sensor size over another or select one protrusion height instead of any other. Indeed, Ohsaki explains that its sensor's width and length—including the board—are important but says nothing about the height of the board. *See* Ex. 1014 ¶[0019]

("the length of the detecting element 2 from the right side to the left side in FIG. 2 is longer than the length from the upper side to the lower side").

124. Dr. Kenny also cites Kondoh, which Dr. Kenny suggests "describ[es] a protrusion…that causes a subject's tissue to deform by a depth of about 2 to 20 mm." Ex. 1003 ¶148 (citing Ex. 1028). But Kondoh states the protrusion's height is 5 mm, which is outside of the claimed range. Ex. 1028 12:33-39, 13:51-55, 14:66-15:3, 16:15-19, 17:25-28, 26:10-14. In addition, Kondoh is contrary to the proposed cover because Kondoh embeds its optical components (11, 12) on top of the "protrusion part" in direct contact with the user's skin (4). *See, e.g.,* Ex. 1028 13:62-64 ("placed in the protrusion"), Fig. 6. Contrary to Dr. Kenny's brief and unexplained citation, to the extent a POSITA would have found Kondoh relevant at all, Kondoh would have led a POSITA to eliminate any protruding convex surface on a cover so that the emitter and detector are placed "as close as possible to the biological body surface." Ex. 1028 13:62-64 ("placed in the protrusion"), Fig. 6.

125. Dr. Kenny also offers testimony to support his assertions without citing specific evidence. Ex. 1003 ¶149. In particular, Dr. Kenny provides no support for his opinion that a height either between 1 millimeter and 3 millimeters or greater than 2 millimeters and less than 3 millimeters "provide[s] a comfortable cover…that prevents slippage." Ex. 1003 ¶[0148]. Such unsupported testimony

does not show that a POSITA would select a "protruding convex surface protrudes a height between 1 millimeter and 3 millimeters" or a "protruding convex surface protrudes a height greater than 2 millimeters and less than 3 millimeters." In my opinion, a POSITA would not have found it obvious to include a cover with a protruding convex surface "wherein the protruding convex surface protrudes a height between 1 millimeter and 3 millimeters" or "wherein the protruding convex surface protrudes a height greater than 2 millimeters and less than 3 millimeters" based on the cited references of Ground 1.

F. <u>Ground 2 Fails For The Same Reasons As Ground 1</u>

126. Ground 2 only addresses dependent claims 19 and 21. Ex. 1003 ¶¶209-212. Dr. Kenny adds Beyer (Ex. 1019) to the combination of references in Ground 1, and asserts that Beyer demonstrates that "PDA/phone device" was "well-known." Ex. 1003 ¶209. Ground 2 thus does not address or fix the deficiencies that I have identified in Ground 1. Ex. 1003 ¶¶209-212. As a result, in my opinion the claims in Ground 2 are nonobvious for the same reasons as I discuss for Ground 1, above (Sections VII.A-D).

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.,	)	
	)	IPR NO. 2020-1520
Petitioner,	)	US PATENT NO: 10,258,265
	)	
-against-	)	IPR NO. 2020-1537
	)	US PATENT NO: 10,588,553
MASIMO CORPORATION,	)	
	)	IPR NO. 2020-1539
Patent Owner.	)	US PATENT NO: 10,588,554
	)	

VIDEO-RECORDED DEPOSITION OF
THOMAS WILLIAM KENNY, JR. PH.D.
VOLUME 1
Zoom Recorded Videoconference
04/22/2021
9:02 a.m. (Pacific Daylight Time)

REPORTED BY: AMANDA GORRONO, CLR
CLR NO. 052005-01

DIGITAL EVIDENCE GROUP
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Masimo Ex. 2006
Apple v. Masimo, IPR2020-01716

A. Part of that that's inside the, the lens, yes, is refracted more towards the center, because the location where it strikes the surface, there is a different angle of incidence because of the curvature of the lens.

Q. Let me ask you a little bit about this claim limitation. If you want to turn back to Page 69. You're discussing here, I think this is a mean path length of light. Do you see that?

A. Uh-huh.

Q. I think you said a moment ago you were calculating a path length. I guess I want to ask you, how did you interpret mean path length for your analysis?

MR. SMITH: Objection; form.

A. So my understanding is that this is a particular but representative example path, and that -- you know, if I'm thinking about what goes on here, the two situations will have the same path length if the angle of incidence is the same, whereas because of the curvature of the lens, the curvature provides a higher angle of incidence for most path

length. So the refractive effect will lead to a short mean of the path on average of the mean.

Q. So what you're showing here is that -- so when --

MR. LARSON: Sorry, strike that.

Q. So what you're discussing here when you say a mean path length, you're talking about the path on average; is that is that fair?

MR. SMITH: Objection; form.

A. So a mean path length mean the same as an average patent length, yeah.

Q. Is that how you're understanding it?

A. My understanding, yes, would be if I repeated this analysis for a multitude of path lengths, I would find that the majority of them would have a shorter path length.

Q. If you go down to Paragraph -- Paragraph 119, you say, "In more detail, I noted above for [1d] how the lens/protrusion of Inokawa, which is used to modify Aizawa's cover, provides a condensing function by refracting the light passing through it."